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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
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Additional inventors are being named on the ______ *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Method and Apparatus for the Surgical Treatment of Congestive Heart Failure

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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☑ Applicant claims small entity status. See 37 CFR 1.27.
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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Respectfully submitted,

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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Methods and Apparatus for the Surgical Treatment of Congestive Heart Failure

Inventors J. Kern Buckner and John T. M. Wright

BACKGROUND OF THE INVENTION

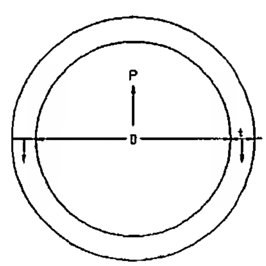
Congestive Heart failure is defined as the failure of the heart to pump blood at a rate to satisfy the requirements of metabolizing tissues. Heart failure is the manifestation of many disease processes affecting the heart and the great vessels, including ischemic cardiomyopathy, viral cardiomyopathy, metabolic or toxic cardiomyopathy and idiopathic cardiomyopathy. Many of these disease processes lead to dilation of the left ventricle as an initial adaptive or compensatory mechanism. This is a short-lived adaptation due to the impaired contractile function of the heart with an inappropriate thinning of myocardium rather than appropriate thickening and, thereby, leading to further left ventricle dilation and cardiac deterioration. Congestive heart failure is a leading cause of death in the United States. With the aging of the population (baby boomers) and the advent of improved cardiovascular therapies, the incidence of congestive heart failure is increasing. Congestive heart failure is most prevalent in people of age 65 or older (incidence 3/1,000 in men age 50-59 and 27/1000 in men age 80-89) and, by 2030, it is estimated that heart failure prevalence will double to 5.7 million cases annually, thereby reaching pandemic proportions. See Starling, R.C. The heart failure pandemic: changing patterns, cost, and treatment strategies. Cleveland Clinic Journal of Medicine. 1998;65:351-358. Within the next ten years it is estimated that 70 million Americans will suffer from congestive heart failure.

As the disease of congestive heart failure progresses the left ventricle further dilates, and the myocardial wall thickness is further diminished. In addition, the left ventricle becomes more spherical and less episoidal, the distance between the papillary muscles and the mitral annulus increases, and the mitral annulus enlarges, especially in the anterior/posterior direction resulting in significant mitral regurgitation. The thinning of the left ventricular myocardium significantly and progressively raises the stress level in the left ventricular wall such that left ventricle function is diminished and eventually ceases to provide sufficient cardiac output to sustain life, resulting in the demise of the patient.

Myocardial wall stress is described by the law of LaPlace...f=P*a/2h (spherical) and f=P*b/h*1-b2/2c2 (ellipsoidal), illustrating the relationship of chamber diameter and wall thickness, where f is the average circumferential wall stress, a is the radius at the endocardial surface, "P" is the intraventricular pressure, "h" is the wall thickness, "b" and "c" the semi-minor and the semi-major axes at the endocardial surfaces. See Braunwald, E. ed. Heart Disease: A Textbook of Cardiovascular Medicine, 4^{th} edition. W.B. Saunders and company, Philadelphia. 1992:370-382. Simply stated, as the left ventricle dilates, wall stress will be maintained normal, if there is a concomitant increase in wall thickness (hypertrophy). However, in cardiomyopathic processes, disease in the myocardium at the myocyte level not only prevents wall thickening, but there is, also, a decrease of wall thickness over time. This, in turn, leads to increased wall stress as described in the law of LaPlace and subsequent further left ventricle dilation without myocardial ability to compensate. See Braunwald, E. ed. Heart Disease: A Textbook of Cardiovascular Medicine. 4^{th} edition. W.B. Saunders and company, Philadelphia. 1992:370-382.

In reality, as the disease progresses, the heart dilates but the thickness of the myocardial wall diminishes. Thus the myocardial wall stress in the initial stage of systole rises very dramatically. The following is a grossly over simplified example (which although holding only for a thin walled vessels) serves to illustrate the point. Thick walled vessels are better described by the LaPlace equation as discussed previously. However, as the left ventricle dilates and the myocardium, becomes thinner the simplistic equation becomes more accurate.

In this over simplified model, the vertical force on the walls of the left ventricle (in systole) per unit length in the direction of the arrow P is D*P, where "P" is the internal systolic pressure in the left ventricle, "D" is the internal diameter of the left ventricle. This force per unit length is balanced by the two wall thickness (t) * the stress in the two myocardial walls (f)



Thus: $P * D = 2t * f$

or $f = P*D/2t$

It follows that as the systolic pressure of the left ventricular or the internal diameter of the left ventricle rise, or the ventricular wall thickness is diminished, the left ventricular wall stress is raised. Typically in congestive heart disease the internal diameter of the

ventricle increases over time and the left ventricular wall thickness decrease over time. In some patients the systolic pressure increases due to systemic hypertension or aortic stenosis. A similar scenario occurs, but for different reasons, in patients with mitral valve regurgitation and concomitant aortic stenosis or systemic hypertension.

In the last two decades there have been significant advances in medical management of congestive heart failure. However, despite these significant improvements in clinical outcomes (death and quality of life) of congestive heart failure, these therapies are limited and as the disease relentlessly progresses the patient either needs to receive a cardiac transplant or will die. Cardiac transplantation presently is the treatment of choice for medically refractory congestive heart failure. Donor organ shortages and patient selection (eligibility) limit this therapy to only a relatively few percentage of patients. Of the approximately 4000 patients on the transplant list per year in the US, only approximately 2200 patients will receive a transplant. See Nemeh, H.W. and Smedira, N.G. "Mechanical treatment of heart failure: the growing role of LVADs and artificial hearts," Cleveland Clinic Journal of Medicine. 2003:70:223-233; see also "Transplant statistics." 11/02/2001. Scientific Registry of Transplant Recipients (available at <<http://ustransplant.org>>).

Several problems face the clinician in treating patients with congestive heart failure. First, and importantly, concerns the determination of how far the disease has progressed and, secondly, when the patient has become a viable candidate for surgery, either for cardiac transplantation or alternative surgical intervention.

Preload (length of stretch of sarcomere at end of diastole) and after load (wall stress during ventricular ejection) are interdependent and physiologic components of

heart function. See Braunwald, E. ed. "Heart Disease: A Textbook of Cardiovascular Medicine," 4th edition. W.B. Saunders and company, Philadelphia. 1992:370-382. Many pharmacological therapies have targeted their efficacy on these parameters by reducing ventricular volumes or cardiac and systemic pressures while other therapies alter the inotropic (contractile force) function of the heart. Medical therapy (neuroendocrine axis, improved expression of contractile proteins, enhanced cellular respiratory control, and decrease in markers of apoptosis and cellular stress) however, has had limited success, not only with the management of symptoms but also in achieving long-term survival benefit..

In an attempt to counter the progression of congestive heart failure in 1996 Batista, recognizing the relentless progression of the disease, described a surgical procedure in which a segment of the left ventricle was removed, thus reducing the overall internal diameter of the heart. See J. Card. Surg. 1996 Mar-Apr;11(2):96-7. Of course, the operative procedure also removed a segment of potentially contractile myocardium, reducing the overall contractive potential of the heart as a whole. Presently, surgical intervention generally consists of a surgical remodeling of the left ventricle to reduce its end-diastolic volume and attempting to re-convert the abnormal spherical shaped ventricle to the near normal episoidal shaped ventricle. However, this usually means the implantation of an akinetic ventricular patch, so the patient's ventricular ejection fraction is seldom normal following surgery. In patients where the mitral annulus has become greatly distorted, usually by elongation it is necessary to implant a rigid type mitral annuloplasty ring. This surgery although helpful in some patients, is not fully effective.

Present surgical procedures for heart failure include transplantation, LV assist devices (pumping), valve replacement or repair, cardioplasty, coronary bypass surgery, and left ventriculectomy. The indications for these procedures encompasses a wide spectrum that must be individualized to patients with moderate disease at variable risk to prevent further deterioration and those limited patients with end-stage disease at very high risk whose very survival depends upon the procedure.

End diastolic external cardiac restricting devices have been used (Acorn Cardiovascular, Inc. CorCap™ , an endocardial support device, is a mesh-like heart "jacket" that is placed around the heart and held in place to prevent any further enlargement (See US Patents 6,582,355; 6,579,226; 6,537,203). This and similar devices, although providing immediately post-operative effective relief for the patient, may probably lead to long term constrictive pericarditis in a significant number of patients. Another end diastolic restricting device has been proposed by Vidlund RM et al. (See US 6,537,198 – Myocor, Inc.). It proposes one or more cables passed through the myocardial wall, passed across the ventricular cavity to exit the opposing myocardial wall. Ends of the cable are intended to be secured using crimped "buttons". The latter approach seems an over simplistic approach to a complex problem. This proposed method is unlikely to provide sufficient myocardial support to the heart.

Alternative mechanical devices are, therefore, necessary and needed. See Gregoric, I. And Couto, W.J. "Surgical treatment of congestive heart failure. congestive heart failure," 2002;8:214-219 Many end-stage congestive heart failure patients may, therefore, benefit from a mechanical device, either as a bridge to transplant or as destination therapy, if they are otherwise ineligible for transplant. See Nemeh, H.W. and

Smedira, N.G. "Mechanical treatment of heart failure: the growing role of LVADs and artificial hearts," Cleveland Clinic Journal of Medicine. 2003:70:223-233; see also Westaby, S. "The need for artificial hearts," Heart. 1996;76:200-206.

Each of the foregoing patents and publications is incorporated herein by reference in its entirety.

It is an object of this invention to provide an implantable device that effectively addresses surgical treatment of congestive heart failure or ventricle (left or right) failure.

It is a further objective of this invention to provide a flexible, contractile inter-ventricular device that restricts dilation of the ventricle (left or right) for the treatment of congestive heart failure.

It is a further objective of this invention to provide a flexible, compressible, non-expansive device that restricts dilation of the ventricle.

It is a further objective of this invention to provide a flexible, compressible, non-expansive device that stores energy during both ventricular systole and ventricular diastole.

It is a further objective of this invention to provide a flexible, compressible, non-expansive device that stores energy during ventricular systole.

It is a further objective of this invention to provide a flexible, compressible, non-expansive device that augments the pumping function of the ventricle (left or right) in systole.

It is a further objective of this invention to provide a flexible, compressible, non-expansive device that aids filling of the ventricle (left or right) in diastole.

It is a further objective of this invention to provide a device that prevents dilation of the mitral annulus.

It is a further objective of this invention to provide a device that prevents axial elongation of the ventricle (left or right) between the mitral valve annulus and the level of the papillary muscles.

Other objectives and advantages of this invention will be more apparent from the detailed description of the device that follows.

SUMMARY OF THE INVENTION

This invention provides implantable inter-ventricular devices. The devices are placed within the left (or right) ventricle of the heart, to remodel the geometry of the heart, to both limit the end-diastolic diameter of the ventricle, and to store energy during systole, to be released in diastole to improve diastolic filling of the ventricle. The devices of the invention are preferably metallic and are preferably, but not necessarily, covered or encapsulated with or by a relatively non-thrombogenic, thin walled flexible outer member, chosen for its relatively non-thrombogenic and minimal tissue in-growth characteristics. Optional diametral cables limit the maximum end diastolic diameter of the left ventricle.

In preferred embodiments, the device comprises an array of bistable bands arranged to form an elliptically shaped cage that approximates the shape of the normal ventricle. In an alternative embodiment, the device comprises a concertina type circular spring secured to the endocardium. One or more circumferential strings limit the maximum diameter of the implanted device. The devices are inserted into the heart

preferably via a surgical incision, and may be preferably implanted in the left ventricle immediately adjacent to and between the papillary muscles and the ventricular aspect of the mitral valve. Implantation sutures may be passed through the ventricular wall and serve to securely anchor the device in place, or alternatively, the device may have a series of "hooks" that engage and retain the device in the ventricle. The devices may be made in various sizes to suit the anatomy and correct the pathology of the patient.

In further embodiments a mitral annuloplasty ring, intended to be implanted sub-annularly, is attached by legs to the ventricular device, thus correcting ventricular circumferential and shape anomalies, as well as correcting axial mitral valve axis to papillary length.

The invention also provides methods for augmenting systolic contraction and diastolic relaxation while maintaining an optimal ventricular elliptical geometry to mechanically reduce myocardial wall stress.

The devices of the invention mechanically augment the active phases of systole and diastole in the cardiac cycle. The devices effectively restore cardiac geometry to a mechanically efficient elliptical shape. Those skilled in the art will recognize that the devices also have beneficial effects in normalizing wall thickness. In restoring an optimal mechanically efficient elliptical cardiac shape, the device allow an effective range of sarcomere length change to maximize resting and active tension states for optimization of stroke volume throughout a large range of after load. Furthermore, in addition to fixing diastolic and systolic volumes, the devices assist the active phases of both diastole and systole by augmenting the active contractile force of diseased myocardium in systole and the relaxation of myocardium in diastole. In systole, maximum systolic emptying is

increased and, in diastole, the devices provide an augmented restoring force that provides "suction" in early diastole to enhance early ventricular filling.

The simplicity and design of the inter-ventricular devices of the invention are such that they are relatively inexpensive to manufacture, relative to the long-term cost of treating patients with congestive heart failure.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows an isometric view of the bistable cage to be implanted in the ventricle in the first bistable or expanded condition.

Figure 2 shows a plan view of the bistable cage to be implanted in the ventricle taken in the direction of arrow **A** in Figure 1.

Figure 3 shows a part cross-section taken along line **BB** of Figure 1.

Figure 4 shows an isometric view of the bistable cage to be implanted in the ventricle in the second bi-stable or contracted condition.

Figure 5 is a plan view of the bistable cage to be implanted in the ventricle taken in the direction of arrow **C** in Figure 3.

Figure 6 shows a part cross-section taken along line **DD** of Figure 4.

Figure 7 shows a cross-sectional view of the left ventricle view of the heart at initial systole with the preferred embodiment of the device implanted within the ventricle.

Figure 8 shows a cross-sectional view of the left ventricle view of the heart at initial systole with the preferred embodiment of the device implanted within the ventricle taken along line **EE** of Figure 7.

Figure 9 shows a cross-sectional view of the left ventricle view of the heart at initial diastole with one preferred embodiment of the device implanted within the ventricle.

Figure 10 shows a cross-sectional view of the left ventricle view of the heart at initial diastole with the preferred embodiment of the device implanted within the ventricle taken along line **FF** of Figure 9.

Figure 11 shows an isometric view of an alternative embodiment of the bistable cage to be implanted in the ventricle in the expanded condition.

Figure 12 shows a plan view of an alternative embodiment of the bistable cage to be implanted in the ventricle taken in the direction of arrow **G** in Figure 11.

Figure 13 shows a side view of an alternative embodiment device using concertina" spring device encapsulated with a non-thrombogenic sheath, and having longitudinally limiting ligatures.

Figure 14 show a plan elevation of the alternative embodiment device shown in Figure 13.

Figure 15 shows an enlarged cross-sectional view of the alternative embodiment device shown in Figure 13 taken in the direction of the line **HH** of Figure 13.

Figure 16 shows an enlarged part cross-sectional view of the alternative embodiment device shown in Figure 13 taken in the direction of line **II** in Figure 14.

Figure 17 shows an side view of the bare "concertina" type spring used in the alternative embodiment device shown in Figure 13.

Figure 18 show an elevation view of the "concertina" type spring alternative embodiment device shown in Figure 13.

Figure 19 shows an enlarged side view of a portion of the bare "concertina" type spring shown in Figure 17.

Figure 20 show an enlarged part elevation of the "concertina" type spring shown in Figure 18.

Figure 21 is a plan view of the extruded sheath.

Figure 22 is an enlarged part cross-sectional view of the extruded sheath taken direction of the arrows JJ of Figure 21.

Figure 23 is an enlarged part cross-sectional view of the outer sheath taken direction of the arrows KK of Figure 24.

Figure 24 is a plan view of an extruded biocompatible encapsulating sheath following the removal of surplus side material.

Figure 25 shows a long axis cross-section through the left ventricle of the heart with the alternative embodiment device implanted.

Figure 26 shows a cross-sectional view of the left ventricle of the heart taken along line LL of Figure 25 with the alternative embodiment device implanted.

Figure 27 shows a cross-sectional view of the left ventricle of the heart taken along line LL of Figure 25 with the alternative embodiment device implanted, but where surgical ventricular reduction has been used.

Figure 28 shows a cross-sectional view of the left ventricle of the heart taken along line LL of Figure 25 with the alternative embodiment device implanted, but where surgical ventricular reduction has been used (and additionally not shown in Figure 25) a portion of the trained latissimus dorsae muscle has been wrapped around the device within the heart.

Figure 29 shows a cross-sectional view of the left ventricle of the heart taken along line **LL** of Figure 25 with the alternative embodiment device implanted, but where surgical ventricular reduction has been used (and additionally not shown in Figure 25) a portion of the trained latissimus dorsae muscle has been wrapped around outside of the left ventricle of the heart.

Figure 30 shows a plan elevation of a further alternative embodiment device incorporating a sub-annular mitral annuloplasty ring. The device has been closed and ligatures tied simulating its implanted configuration.

Figure 31 shows a side elevation view of the further alternative embodiment device incorporating a sub-annular mitral annuloplasty ring taken in the direction of arrow **M** in Figure 30.

Figure 32 shows a side elevation of the cross-sectional view of the further alternative embodiment device incorporating a sub-annular mitral annuloplasty ring shown taken in the direction of arrow **N** in Figure 30.

Figure 33 shows an enlarged part cross-sectional view a portion of the further alternative embodiment device incorporating a sub-annular mitral annuloplasty ring taken along line **OO** of Figure 30.

Figure 34 shows an enlarged part cross-sectional view a portion of the further alternative embodiment device incorporating a sub-annular mitral annuloplasty ring taken along line **PP** of Figure 30.

Figure 35 shows a side elevation view of the "concertina" type spring used in the further alternative embodiment device incorporating a sub-annular mitral annuloplasty shown ring Figure 30, prior to the forming of the hoop shown in Figure 33.

Figure 36 shows an plan elevation view of a portion of the “concertina” type spring shown in Figure 35, prior to the forming of the hoop shown in Figure 33.

Figure 37 shows a long axis cross-sectional view of the left ventricle of the heart with the further alternative embodiment device incorporating a sub-annular annuloplasty ring implanted.

Figure 38 shows a cross-sectional view of the left ventricle of the heart taken along line **QQ** of Figure 37.

Figure 39 shows a cross-sectional view of the left ventricle of the heart taken along line EE of Figure 7 with the further alternative embodiment of the invention shown in Figure 1 that incorporates a sub-annular mitral annuloplasty ring.

Figure 40 shows a long axis cross-sectional view of the left ventricle and left atrium taken along line RR of Figure 39.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

This invention provides implantable devices that act as flexible and compressible pump assemblies to augment systolic contraction and diastolic relaxation while maintaining an optimal ventricular elliptical geometry to mechanically reduce myocardial wall stress. The invention also provides methods for augmenting systolic contraction and diastolic relaxation while maintaining an optimal ventricular elliptical geometry to mechanically reduce myocardial wall stress.

In the preferred embodiment the device comprises an array of bands comprised of materials including but not limited to metals or alloys such as Nickel Titanium alloy, stainless steel, Titanium, or other similar property metals; or the device is comprised of

laminates or other materials having similar hard and flexible characteristics to such metals and alloys. Most preferably the device is comprised of super elastic grade Nickel Titanium alloy (a superelastic "memory metal depending upon its composition and heat treatment conditions) otherwise known as "Nitinol." The bands may be comprised of simple strips, or comprise of a bundle of monofilaments arranged optimally in rectangular circular elliptical or other suitable cross-section.

In the preferred embodiment of the invention the bands are arranged in an elliptically shaped cage to approximate the shape of the normal ventricle (left or right). The cage is comprised of circumferential as well longitudinal elements that during implantation are anchored to the myocardial wall at specified sites, preferably using surgical sutures. The act of suturing the cage into the ventricle restricts the diastolic chamber size thereby reducing initial systolic myocardial wall stress.

The longitudinal bands of the cage are formed so as to be able to shift from a monostable to bistable state. The geometry of the device fashions the bands such that the bands have a resting state of curvature, thereby establishing an oscillating bistable state. The bands in a bistable state, and anchored to the myocardium, are sensitive to the lateral forces of a contracting left ventricle, initiating movement in the same direction. The contracting and, therefore, shortening left ventricle also applies a powerful axial force to the longitudinal axis of the device. These two forces working in concert, generate a lateral displacement of the elements of the device into the opposite bistable direction, releasing stored energy, and creating a powerful pumping force. The changed resting state of the longitudinal bands or monofilaments, in the other bistable and expanding state, are sensitive to the lateral forces generated by the diastolic ventricular relaxation,

initiating movement of the longitudinal elements in the same direction and opposite bistable state. The relaxing and elongating ventricle facilitate the movement of the longitudinal element in the direction of the opposite bistable state. The release of this stored energy augments the ventricular wall expansion of diastole and thereby creates a "sucking" force to enhance left ventricular filling and restore optimal diastolic function. Furthermore, the longitudinal structure of the device applies a restrictive force to fix the end-diastolic dimensions of the left ventricle to a more optimal size, shape and volume and, thereby, reduces myocardial wall stress during early systole. Optional transverse cables with loops retained firmly against opposing longitudinal bands restrict end diastolic diameter of the heart.

In an alternative embodiment the device is comprised of a flat strip of metal, preferably of a biocompatible nature with a long fatigue life, formed into distinct lengths of concertina shaped spring, separated by linear lengths, and the whole spring member encapsulated within a low thrombogenic, low tissue in-growth material (such as expanded Poly Tetra Fluro-ethylene (PTFE) sheath. The metallic portion (a part concertina shaped spring, part linear portion) is preferably formed of a biocompatible metal with a long fatigue life, including but not limited to MP35N alloy and Titanium Nickel (Ti Ni) alloy (a "Memory metal"). The sheath encapsulating the spring is preferably of expanded PTFE, a material with proven biocompatibility and with low tissue ingrowth. One or more circumferential ligatures, positioned on one or both sides of the spring member and within the biocompatible sheath are tied together at implantation to limit the circumference of the implanted spring device, and therefore limit the end diastolic diameter of the, the ventricle. The device is surgically placed in the

endothelium, and implanted around the periphery of the (surgically adjusted) endocardium. The circumferential size of the device is determined by the surgeon during implantation by selection of the free length of the actual device to be implanted, and, during implantation by adjusting and tying the corresponding ligature ends to thus limit the maximum diameter of the device, sutured into place. Depending upon the patient's disease condition it may be necessary to remove a section of the ventricle, thus reducing end-diastolic ventricular diameter and myocardial wall stress. During ventricular systole the spring becomes compressed, and during diastole the spring applies an outwards radial force on the ventricular wall that aids in diastolic filling.

Referring now to the drawings wherein like numerals indicate like elements, the various embodiments of the invention will now be described in more detail. Note that in the following embodiments of the invention, the left ventricle is the target for intervention. It will be understood by one skilled in the art that the methods and devices of the invention may also be readily used in the right ventricle, or in both ventricles.

Figure 1 shows an isometric view of the bistable cage **10** in the expanded condition. Figure 2 shows a plan view taken in the direction of arrow **A** of Figure 1. The cage material is formed during manufacture to be mechanically bistable, generally because of the cage material characteristic curved cross-section of the limbs of the cage (Figure 3). The cage is bounded at its lower end by hoop **15** and at the upper end by an overlapping open hoop **20**. The overlapping member **25** (overlapping **22**) allows the overlapping portion to be sprung open to allow the chordae tendineae to be passed into the cage during implantation. Holes **28, 29** in overlapping member **25** have corresponding

holes (not shown **22, 23**) through which a suture may be passed to retain the upper hoop closed at implantation. In one embodiment of the invention the cage has four curved longitudinal strut members **30, 31, 32, 33**, which are shown in the expanded bistable state. However, those skilled in the art will recognize that two, three, five, six or more struts could be used. Clearly the dimensions of the bistable cage, including the length, annular diameter, apical diameter, and degree of curvature will vary depending upon individual patient's anatomy and pathology. The upper vertical edge **27** of longitudinal strut **30** lies behind overlapping portion **25** of upper open hoop **20**.

Figure 4 shows the cage **10** in its contracted bistable state. The four curved longitudinal strut members **40, 41, 42, 43** have undergone a change of state from the convex barrel like shape shown in Figure 1 to a concave waist like shape shown in Figure 4. Figure 6 is a cross-section taken along line **DD** of Figure 4. The slight convex outer curve **35** shown in Figure 3 has transformed into a slight concave curve **45** shown in Figure 6. Figure 7 shows a cross-sectional view of the left ventricle with the preferred embodiment of the invention implanted, and Figure 8 shows a cross-sectional view of the left ventricle, taken along line **EE** of Figure 7. Both Figure 7 and Figure 8 show the left ventricle in the early systolic phase, with the mitral valve **51** closed and the aortic valve **50** open. Figure 7 shows the left myocardium **52**, aortic outflow tract **54**, and the left atrium **55**, left ventricular apex **56**, and the aortic valve **50**. The mitral valve mechanism consists of the two papillary muscles **60, 61**, the two sets of chordae tendineae **64, 65** and the anterior **68** and posterior **70** leaflets of the mitral valve. The bistable cage **10** is, in the preferred embodiment of the device is secured by means of suitable sutures **75**, passed through the myocardium **52** and supported by external epicardial pledget members **80**.

The sutures are conveniently terminated by epicardial knots **85** placed over the epicardial pledgets **80**. Upper hoop **20** is retained closed by suture **84** terminated by knot **89**, and secured to the mitral annulus by a series of sutures **74**, reinforced with pledgets **73** and terminated in knots **72**. Lower hoop **15** is secured to the myocardium near its apex by suitable sutures **79**, passed through the myocardium **52** and supported by external epicardial pledget members **86** and secured by knots **87**. Optional flexible cables **81, 82** terminated with loops **83** and knots **88** are retained firmly against members **30, 32** and **31, 33** respectively by implanting sutures **75**. Optional flexible cables **81, 82** serve to restrict the maximum diameter of the device, and hence limit the end diastolic diameter of the heart. Cables **81, 82** may be of expanded Poly Tetra Fluro-ethylene (PTFE), a material that has been used successfully to replace chordae tendinae in mitral valve repair operations.

Figure 9 shows a cross-sectional view of the left ventricle, and Figure 10 shows a cross-sectional view of the left ventricle, taken along line FF of Figure 9. Both Figure 9 and Figure 10 show the left ventricle in the early diastolic phase, with the mitral valve **51** open and the aortic valve **50** closed. The bistable cage 10 is in its second bistable state as shown in Figures 4 and 5.

Figures 11 and 12 show alternative embodiments of the invention shown in Figure 1, in which the inextensible near-apical lower member **15** of Figure 1 has been replaced by a convoluted member **90** that allows its effective diameter to expand and contract in response to applied forces. The convoluted member **90** is composed of four plain segments **91, 92, 93, 94** located end the lower end of the longitudinal members **95, 96, 97, 98**. Between plain segments **91** and **92** lies convoluted segment **100**, and likewise

between plain segments **92** and **93** lies convoluted segment **101** and between plain segments **93** and **94** lies convoluted segment **102**, and between plain segments **94** and **91** lies convoluted segment **103**. Each convoluted segment contains multiple convex portions illustrated by **104, 105** multiple concave portions illustrated by **106** joined by multiple linear sections illustrated by **107, 108**. Figure 11 shows three convex sections, four concave sections joined by six linear sections. However, those skilled in the art will understand that more or fewer convolutions could be used with effect. The illustration in Figure 11 is not meant to limit the number of convolutions used.

In another embodiment of the invention as depicted in Figures 11 and 12, one or more of the longitudinal members **95, 96, 97, 98** comprise hour glass-shaped section(s), preferably located near to the upper and lower ends of the longitudinal members. The recesses forming the hour-glass sections **111, 112, 113, 114, 115, 116, 117, 118** are located near the lower end of the longitudinal members, and recesses **121, 122, 123, 124,** (**124** is hidden from view) **125, 126, 127** and **128** are located near the upper ends of longitudinal members **95,96,97 98** . The hour-glass recesses, being areas of increased flexibility, cause the longitudinal member to flex from one stable position to second stable position at these predetermined areas. Although one hour-glass recess is shown near each end of the longitudinal members, those skilled in the art will recognize that more or less than two recesses may be placed at various locations along a longitudinal strut member, depending upon the material characteristics and dimensions (length, width and thickness) of the longitudinal strut member. The longitudinal legs **95, 96, 97, 98**) may be unitized with the convoluted lower member **90**, or for ease of manufacture may be joined to member **90** by rivets or using an adhesive, or preferably by electron beam or

laser welding as shown in Figures 11 and Figure 12, the welds being located at **130, 131, 132, 133, 134, 135, 136, 137**. Also for convenience of manufacture lower member **90** may be likewise made from flat sheet material and joined by electron beam or laser welding along a line **139**, shown in Figure 11.

An alternative embodiment of the invention is shown in Figures 13 and 14 that are, respectively, a side view and a plan view of the implantable spring member device **200**, having a first end **201** and a second end **202** and that comprises of an interrupted "concertina" type spring member sections **205, 210**, and **215** separated by planar sections **220, 225**.

As shown in Figure 14 longitudinal ligatures **230, 235** are partially enclosed in multiple short tubes **212** situated on thefirst side and forming part of the sidewalls of sheath **203,** and other multiple short tubes **213** situated on the second side and forming part of the sidewalls of sheath **203**. Additionally, two pairs of long tubes, **216, 217, 218, 219**, also form part of the sidewalls of the sheath. Ligature **230** has a first tail **231** and a second tail **232**. Ligature **235** has a first tail **236** and a second tail **237**.

Figure 15 shows an enlarged cross-sectional view through sheath **203** taken along line **HH** of Figure 13. Figure 16 shows an enlarged partial cross-sectional view through sheath **203** taken along line **II** of Figure 14.

Referring to Figure 15 inner spring member **240** is enclosed within biocompatible sheath **203** that has an upper wall **263** and a lower wall **265** and is bounded by integral tubes **212, 213** in the section shown in Figure 15. Tubes **212, 213**, have lumens **270, 272** respectively, through which ligatures **230, 235** are free to pass.

Internal spring **240,** shown in side elevation in Figure 17 and in plan view in Figure 18, has a first end **241** and a second end **242.** Spring member **240,** has concertina type spring sections **205a, 210a, 215a** separated by planar sections **220a, 225a.** These sections correspond to similar sections in Figures 13 and 14, e.g. the section of the spring member designated as **205a** in Figure 17 is contained within section **205** of the device shown in Figure 13. Likewise other similarly designated sections correspond accordingly. Figure 19 and Figure 20 show respectively greatly enlarged part side and plan elevations of spring section **205a** shown in Figures 17 and 18, and a small portion of planar section **220a,** likewise shown in Figures 17 and 18.

Referring now to Figures 19 and 20, which are greatly enlarged side and plan elevation views of section **205a** of Figures 17 and 18, spring member **240** has a short planar portion **253** adjacent to first end **241**, rounded root **255,** flank **260**, and rounded crest **265** that are linearly arrayed to form successive portions of the concertina springs shown in Figures 17 and 18.

Figure 21 shows a plan view of the extruded length of extruded flexible member **250** used to manufacture the flexible biocompatible sheath, cut to the required length having first end **251** and second end **252.** The sheath is preferably made from a low thrombogenic, low tissue in-growth material such as extruded and expanded Poly Tetra Fluro-ethylene (PTFE). Alternatively, a medical grade of woven, knitted or braided Polyester cloth could be used.

Figure 22 shows an enlarged cross-sectional view taken along line **JJ** of Figure 21. Central cavity **260,** which contains spring member **240** is bounded by upper wall **262** having upper face **263**, lower wall **264** having lower face **267** and integral tubes **266** and

268. Tube **266** has lumen **270** and tube **268** has lumen **272**. Excess material in tubes **266, 268** is later cut away (as indicated by cross-hatched section **271, 273** in Figure 21 delineated in part by the dashed lines **274, 275** that emanate from the final form shown in Figure 24) to form the final sheath **203**. The other delineations of the cut-outs are shown in Figure 23, which shows an enlarged cross-sectional view taken along line **KK** of Figure 24. The view shows that sections **266, 268** have been partially cut away leaving vertical faces **277, 277a, 277b** and **278, 278a, 278b** (Figure 24) respectively. Only one pair of cut-out delineations are indicated on Figure 21 but it should be clear to one skilled in the art that the cut-out procedure is repeated as appropriate along the entire length of the sheath.

The spring member is preferably made from Nickel Titanium (Ni Ti) alloy, MP35N alloy, or a similar "memory metal" alloy or metal, having significant and fatigue life. As the average age of the patient expected to be approximately in the range of 60 – 80 years old with a probable mean age of 70 years old, with a natural life expectancy of another 10 years, and on average, the human heart beats approximately 45 million times a year, the optimum fatigue life of the device is preferably at least 450 million cycles.

Preferably the spring material is memory set to its final form shown in Figure 17 at below operating room temperature (typically 65°F). Following suitable heat treatment of the material at sub-operating room temperatures the spring may be straightened (or near straightened) and the extruded and trimmed PTFE sheath **203** shown in Figure 23 slid over the then straight metal strip. On re-warming to a temperature above its transition temperature the flat spring reconfigures to its pre-determined semi-convoluted form shown in Figure 17 and the device takes on the form shown in Figure 13. The two

side ligatures **230, 235,** preferably also of expanded PTFE, are then passed though all side tubes and the end trimmed to produce convenient suture tails **231, 232, 236, 237**. Finally walls 262 and 264 at end 252 and 254 are pulled and sewn to complete the device.

The thickness of the spring is preferably approximately 0.5 mm thick but may be in the range 0.25 mm to 1.0 mm in thickness. The width of the spring is preferably about 8 mm wide but may be in the range 3 mm – 20 mm in width. The concertina spring has convex radii **255** of approximately 1.5 mm and concave radii **265**, of approximately 1 mm, although, clearly the radii may be varied, especially depending upon the thickness of the spring material and the Young's Modulus of the spring material, which is preferably of a biocompatible nature, with a long fatigue life, formed into a concertina shaped spring, encapsulated within a suitable sheath **203**.

The spring member device is implanted in the left ventricle, adjacent to the endocardium and proximal to the papillary muscles (preferably just above, or alternatively just below), via an incision through the left ventricle wall, and implanted, in conjunction, if necessary, with appropriate left ventricular reduction.

Various spring member device lengths may be made available. The surgeon can select, either preoperatively, or during surgery, the most appropriate overall length of the device. Factors influencing selection include the patient's body surface area, weight and sex, and the degree of left modeling required to achieve near left ventricular normality.

Referring now to Figures 25 and 26, Figure 25 shows a sections through the long axis of the left ventricle (the right ventricle is not shown) with the spring member device shown in Figures 13 and 14 implanted. Figure 26 shows a cross-sectional view of the left ventricle taken along line **LL** of Figure 25. The device **200** is passed behind the chordea

tendinae, the two ends **201**, **202** are bought together and the tails **231**, **232** of ligature **230** are tied, likewise the tails **235**, **236** together to form knots forming knots **290**, **292**, the device forming a near circular "concertina" type spring as shown in Figure 25. The device is then rotated about the long axis of the left ventricle so that the plane sections **220**, **225** lie adjacent to the papillary muscles in the left ventricle. A series of sutures **295** are passed through the wall of the left ventricle to firmly attach the device to the left myocardium. The sutures are buttressed on the epicardium by a series of bridged pledgets **296** or single pledgets **297**, the sutures being terminated in knots **298.** The myocardial incision is then closed, and the operation completed.

The circumferential ligatures **230**, **235**, preferably of a low thrombogenic, strong material such as expanded PTFE of braided polyester, positioned on one or preferably both sides of the spring member, and the individual end of each ligature may are tied to its other end at implantation, to limit the diameter of the implanted device, and hence the inner maximum diameter (and therefore peak myocardial stress) of the left ventricle.

Figure 27 shows a transverse cross-sectional view of the left ventricle of the heart (similar to that taken along line **LL** of Figure 25) with the spring member device **200** implanted, but where surgical ventricular reduction has been carried out. A section of the left ventricle has been removed, the excised edges of the endocardial wall have been bought together to form junction **280**, which are retained by the securing sutures illustrated by **281** terminating with suitable pledgets such as **296** or **297** and knots **282**. The position of the ventricular incision is illustrative only, the actual location depends on the pathology of the patient and the choice of surgical repair techniques is at the discretion of the surgeon.

Figure 28 shows a transverse cross-sectional view of the left ventricle of the heart (similar to that taken along line **LL** of Figure 25) with the spring member device **200** implanted, but where surgical ventricular reduction has been made and a portion of the trained latissimus dorsae muscle **285** has been wrapped around the device within the heart. Pacing electrodes (not shown) place on the latissimus dorsae muscle and connected to a pacemaker cause the muscle to contract synchronously with that of the myocardium.

Figure 29 shows a cross-sectional view of the left ventricle of the heart taken along line **LL** of Figure 25 with the spring member device implanted, but where surgical ventricular reduction has been made and a portion of the trained latissimus dorsae muscle **285** has been wrapped around outside of the left ventricle of the heart. Pacing electrodes (not shown) place on the latissimus dorsae muscle and connected to a pacemaker cause the muscle to contract synchronously with that of the myocardium.

Figure 30 shows a plan elevation of an additional embodiment **300** of the spring member device **200** previously described, but that incorporates a sub-annular mitral annuloplasty ring **304**, that is attached to the planar sections **320**, **325** by struts **306, 307**. Figure 30 shows the spring member/annuloplasty device in its final circular form, where the four suture tails **331, 332** and **336, 337** have been tied to form knots **390, 392** (shown later in Figure 37).

Figure 31 shows a side elevation of the spring member/annuloplasty device taken in the direction of arrow **M** in Figure 30. Figure 32 shows a side elevation of the spring member/annuloplasty device taken in the direction of arrow **N** of Figure 30. Figure 33 shows an enlarged part side section taken along line **OO** of Figure 30. Figure 34 shows

an enlarged part side section of the annuloplasty ring member **304** taken along line **PP** of Figure 30. Strut **307** inner metallic leg member **405** terminates at its upper end with hoop **450** and overlapping length

As shown in Figures 30, 31 and 32 longitudinal ligatures **330, 335** are partially enclosed in a series of a multitude of short tubes **312** situated on first side and forming part of the sidewalls of sheath **303,** and a second set of short tubes **313** situated on the second side and forming part of the sidewalls of sheath **303**. Additionally, two pairs of long tubes, **316, 317, 318, 319,** also form part of the sidewalls of the sheath **303**. Ligature **330** has a first tail **331** and a second tail **332.** Ligature **335** has a first tail **336** and a second tail **337** (not shown).

Internal spring **340,** shown in side elevation in Figure 35 and in plan view in Figure 36, has a first end **341** and a second end **342.** Spring member **340,** has concertina type spring sections **305a, 310a, 315a** separated by planar sections **320a, 325a.** These sections correspond to similar sections in Figure 30, e.g. the section of the spring member designated as **305a** in Figure 35 is contained within section **305** of the device shown in Figure 30. Likewise other similarly designated sections correspond accordingly. Referring now to Figure 35, spring member **340** has a short planar portion **353** adjacent to first end **341,** rounded root **355,** flank **360,** and rounded crest **365** that are linearly arrayed to form successive portions of the concertina springs shown in Figures 35. Long planar sections **320a, 325a** each have leg members **405, 410.** Leg members have a tapered length **415, 420,** and a short narrow parallel length **425, 430.** The leg members are bent at points **435, 440** at an angle of approximately 15°; the actual angle depends upon the relative dimensions of the device, the size of the annuloplasty ring and the axial distance

from the mitral annulus and the papillary muscles. The short narrow parallel lengths **425**, **430** are formed to produce a retaining hoop **450** with an overlapping section **455**. Hoop **450** is formed, as shown in Figure 35, to closely match that of the annuloplasty ring core **445.**

As with the basic spring member device **300**, the spring material in the spring member/annuloplasty device is preferably comprised of a high fatigue limit metal alloy, most preferably of super elastic grade of Nickel Titanium alloy (a super-elastic "memory" metal, depending upon its composition and heat treatment conditions) otherwise known as "Nitinol," or a metal or alloy having equivalent properties. The optimum fatigue life of the spring member/annuloplasty device is preferably at least 450 million cycles.

The thickness of the spring in the spring member/annuloplasty device is preferably approximately 0.5 mm thick but may be in the range 0.25 mm to 1.0 mm in thickness. The width of the spring is preferably about 8 mm wide but may be in the range 3 mm – 20 mm in width. The concertina spring has convex radii **355** of approximately 1.5 mm and concave radii **365**, of approximately 1 mm, although, clearly the radii may be varied, especially depending upon the thickness of the spring material and the Young's Modulus of the spring material, which is preferably of a biocompatible nature, with a long fatigue life, formed into a concertina shaped spring, encapsulated within a suitable sheath **303**. The sheath is preferably made from low thrombogenic, low tissue in-growth material such as extruded and expanded Poly Tetra Fluro-ethylene (PTFE). The device is implanted in the left ventricle, adjacent to the endocardium and proximal to the papillary muscles (preferably just above, or alternatively just below), via an incision through the

left ventricle wall, and implanted, in conjunction, if necessary, with appropriate left ventricular reduction.

Various device lengths would be made available. The surgeon would select, either preoperatively, or during surgery, the most appropriate overall length of the device. Factors influencing selection would include the patient's body surface area, weight and sex, and the degree of left modeling required to achieve near left ventricular normality.

Preferably the concertina spring with the upper annuloplasty ring retaining ring hoops material are memory set to the final form shown in Figure 35 and Figure 33 at below operating room temperature (typically 65°F). Following suitable heat treatment of the material at sub-operating room temperatures the spring may be straightened (or near straightened). The annuloplasty ring retaining hoops **450**, with overlapping sections **455**, are partially distorted just sufficient to allow the annuloplasty ring core **445** to be snapped into position.

The annuloplasty ring **304** is shown as an open "D" shaped ring, however those skilled in the art will understand that a semi-circular or semi-elliptical may be used. It is necessary that the ring be open so that the chordae tendinae may be passed through the open section during implantation. The ring is preferably sufficiently strong and rigid to restore the mitral annulus to its pre-diseased size and shape and hence restore the coaptation of the mitral valve leaflets should the annulus have become pathologically distorted, and further to prevent future distortion or enlargement of the mitral annulus. The structural core **445** of the annuloplasty ring **304** may be comprised of a suitable biocompatible material such as ceramic, plastic or metal. Metals such as stainless steel, Titanium or Nickel Titanium alloy (*e.g.* Nitinol), however, preferably the annuloplasty

ring core should be of similar material to the spring member **340** and strut members **405, 410** to avoid galvanic corrosion.

The convoluted spring member **340** may be covered using a similar sheath to the extruded and trimmed sheath shown previously in Figure 23. However, because the legs **415, 420** protrude from spring member **340** it is not possible to slide the sheath into place. It is therefore preferable to divide the sheath into three lengths **466, 467, 468**. Firstly, two equal lengths of sheath **466, 467** are pushed, one onto each end section. Secondly, the third length **468** is slit, preferably midway along wall **264** (the wall 264 is shown in Figure 15), opened out, placed on the mid section of convoluted spring **340**, and the cut edges sewn together to form longitudinal seam **460**, shown in Figures 31 and 32. Sheath member **468** is sewn to sheath member **466** at sheath seam **462**, and to sheath member **467** at sheath seam **463** (shown in Figure 37).

Once the sheath **303** is in place the annuloplasty ring core **455** is snapped into hoops **405** and the device heat treated to a temperature above the material transition temperature. The flat spring reconfigures to its pre-determined semi-convoluted form and the hoops **450** firmly grasp the annuloplasty ring core **455**. Junction **460** may be fixed by adhesive, welding, silver soldering, riveting or other suitable means.

The struts leg members **405, 410** may be covered with a similar biocompatible covering **470** which is sewn to sheath **303** at leg seams **464** and **465,** and having top seams **475** and **476**. Annuloplasty ring **304** is shown in cross section in Figure 34 typically has a rigid central core member **445**, that may, optionally have a resilient covering **448** of a suitable biocompatible material such as medical grade silicone rubber and an outer sheath **449** of a suitable biocompatible material such as polyester woven,

knitted cloth or braided tube. Finally the two side ligatures **330**, **335**, preferably also of expanded PTFE, are then threaded through successive short and long tubes to complete the device.

Referring now to Figures 37 shows a sections through the left ventricle (the right ventricle is not shown) with the device shown in Figure 31 implanted. An incision (not shown) is made in the left ventricle and the device inserted. The chordae tendinae are passed through the gap in the "D" shaped mitral annuloplasty ring, the device **300** is passed behind the chordae tendinae, the two ends **301**, **302** are bought together and the tails **331**, **332** of ligature **330** **are** tied, likewise the tails **335**, **336** together to form knots forming knots **390**, **392**, the device forming a near circular "concertina" type spring as shown in Figure 25. The device is then rotated about the long axis of the left ventricle so that the plane sections **316**, **317** lie adjacent to the papillary muscles in the left ventricle. A series of annuloplasty sutures **493**, with pledgets **492**, and secured by knots **494**, are passed through the mitral annulus and around the annuloplasty ring **304**. Figure 37 shows annuloplasty sutures placed in the left atrium, however some surgeons might prefer to pass the sutures from the ventricular aspect. Sutures **495** are passed through the wall of the left ventricle to firmly attach the device to the left myocardium. The sutures are buttressed on the epicardium by a series of bridged pledgets **496** or single pledgets **497**, the sutures being terminated in knots **498.** The myocardial incision is then closed, and the operation completed.

Figure 38 shows a cross-sectional view of the left ventricle of the heart taken along line **QQ** of Figure 37 with the further alternative embodiment **300** of the invention that incorporates a sub-annular mitral annuloplasty ring **304** implanted.

Figure 39 shows a cross-sectional view of the left ventricle of the heart taken along line EE of Figure 7 with the further alternative embodiment **500** of the invention **10** that incorporates a sub-annular mitral annuloplasty ring **510** attached to upper hoop **505**. Figure 39 shows the cage having three curved longitudinal strut members **520, 525, 530,** but two, four or more struts could be used. Upper hoop **505** is integral to longitudinal struts **520, 525, 530** (as is lower hoop **506** shown later in Figure 40). Extension members **535, 540, 545,** also integral to upper hoop **540,** are joined to mitral annuloplasty ring **510.** Various method of joining may be employed such as laser or electron beam welding, silver soldering or brazing, or adhesives or by the use of hoops as shown in Figure 33. A series of sutures **550,** with pledgets **555** and secured by knots **560** secure the longitudinal struts to the ventricular wall. A second series of annuloplasty sutures **565** are passed through the mitral annulus and around the annuloplasty ring **510.** Optional flexible cables **580** are terminated by loops **582** and knots **583.** The loops **582** may be retained by implanting sutures **550,** or attached by suitable means to the longitudinal struts **520, 525, 530.** The cables are joined together approximately in the center of the ventricle by central cable knot **585.** The purpose of the optional cables is to limit the end-diastolic diameter of the left ventricle.

Figure 40 shows a long axis cross-sectional view of the left ventricle and left atrium taken along line RR of Figure 39. Annuloplasty ring 510 is mounted sub-

annularly using sutures **565**, supported by pledgets **570** and terminated with knots **575**. An advantage of this device is that it may be implanted by passage through the mitral valve, obviating the need to open the left ventricle.

ABSTRACT

The invention provides methods and devices for remodelling and restricting further enlargement of the ventricle in patients with congestive heart failure or ventricle (left or right) failure. The methods and devices return the ventricle to its optimal elliptical shape, reducing wall stress. The methods and devices restrict end diastolic myocardial diameter, mitral annulus dilatation (or restoration the mitral annulus where the annulus has been pathologically enlarged) and maintain or reestablish pathological increase in mitral annulus to papillary muscle axial dimension.

The devices of the invention store certain energy derived from early systolic contraction of the heart and aids end systolic contraction. In the preferred embodiment of the invention the devices also store certain energy derived from early diastole and releases a portion of said energy to enhance the subsequent end diastolic filling phase of the heart. An alternative embodiment utilizes a near circular "concertina" type spring member, enclosed within a non-thrombogenic sheath with minimal tissue ingrowth potential, stores energy derived from systolic contraction of the heart and releases a portion of said energy to enhance the subsequent diastolic filling phase of the heart. In some patients it may be advantageous to implant a segment of the trained and paced latissimus dorsae muscle around, or partially around, the heart or around or partly around the device within the heart to aid in systolic contraction. Mitral annuloplasty rings may be incorporated into the devices to remodel the mitral annulus.

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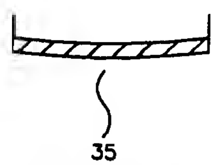

Figure 3

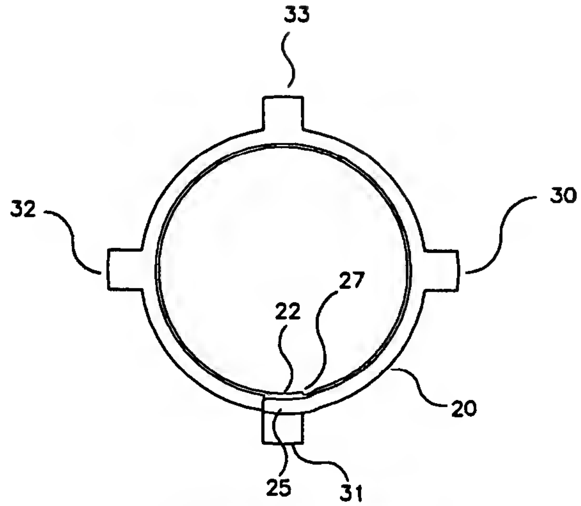

Figure 2

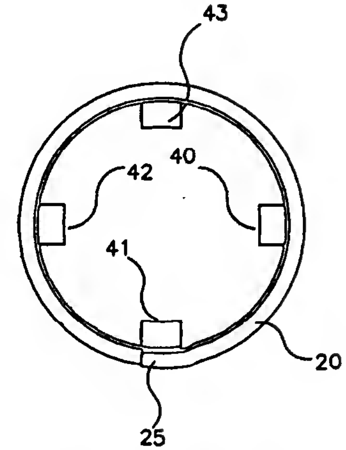

Figure 5

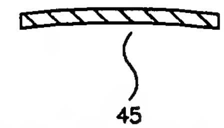

Figure 6

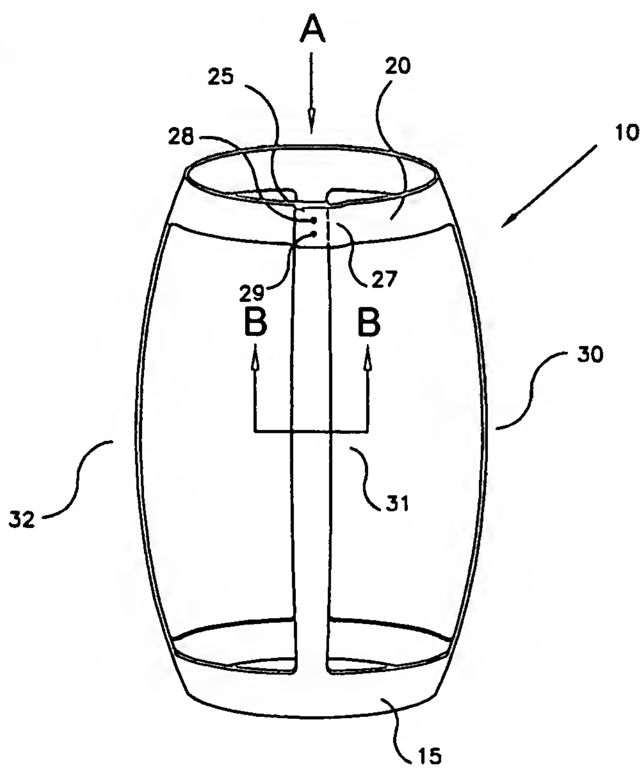

Figure 1

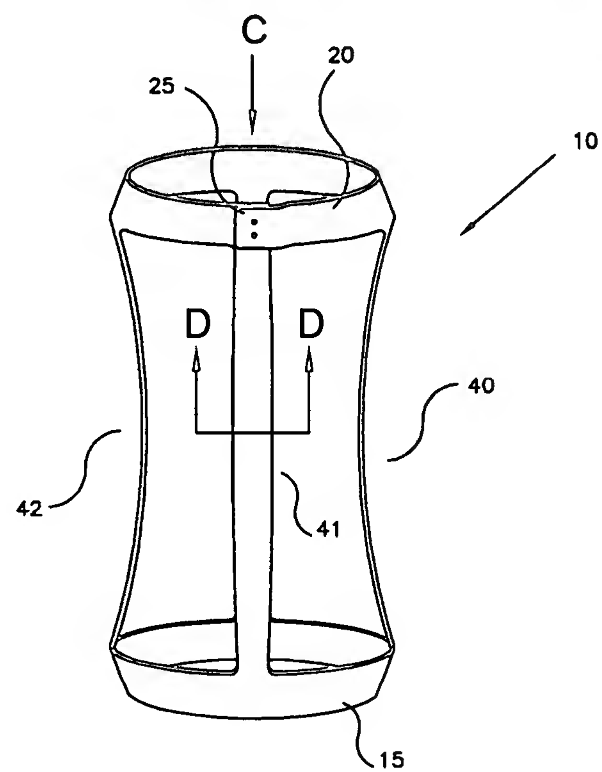

Figure 4

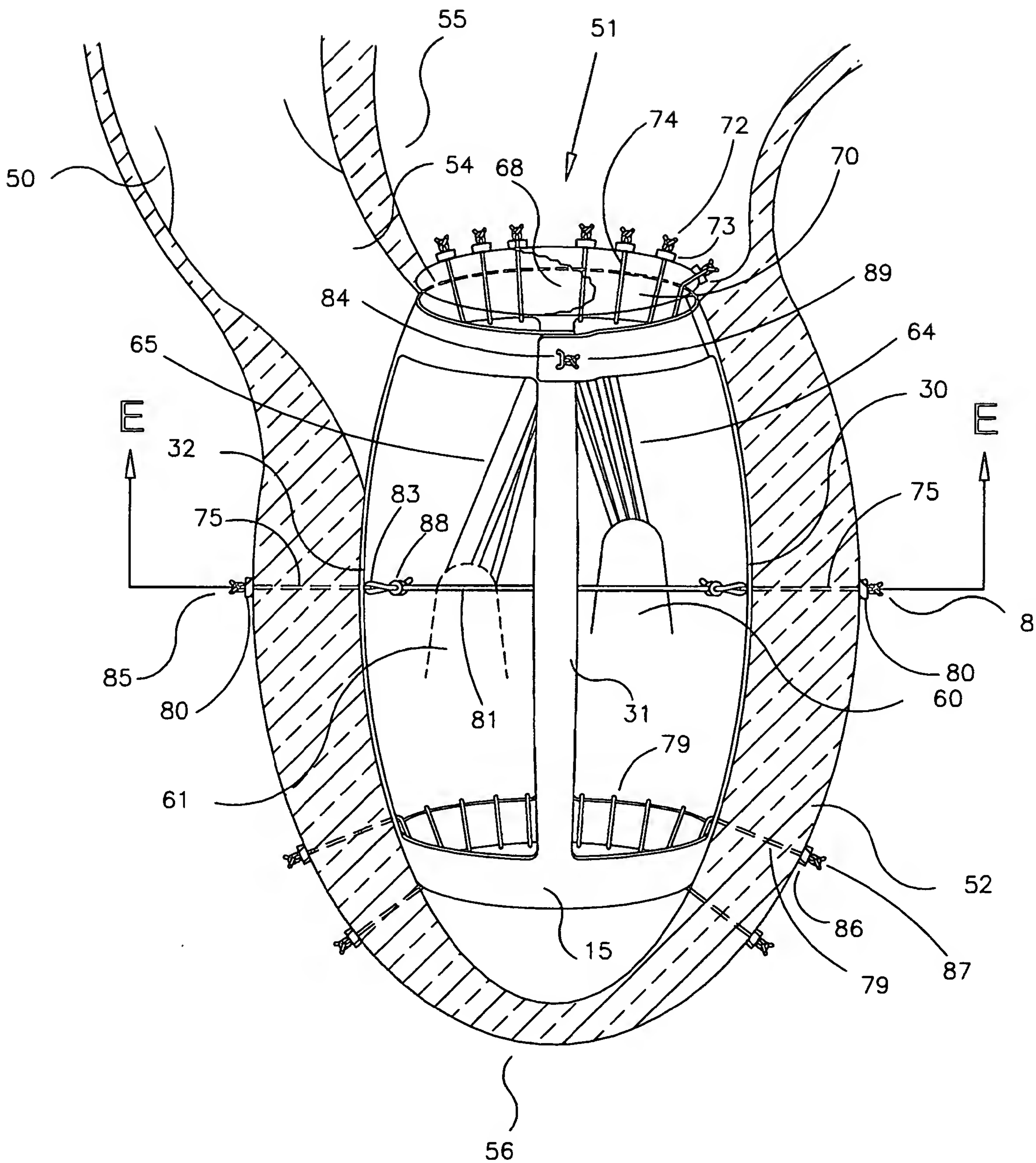
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Figure 7

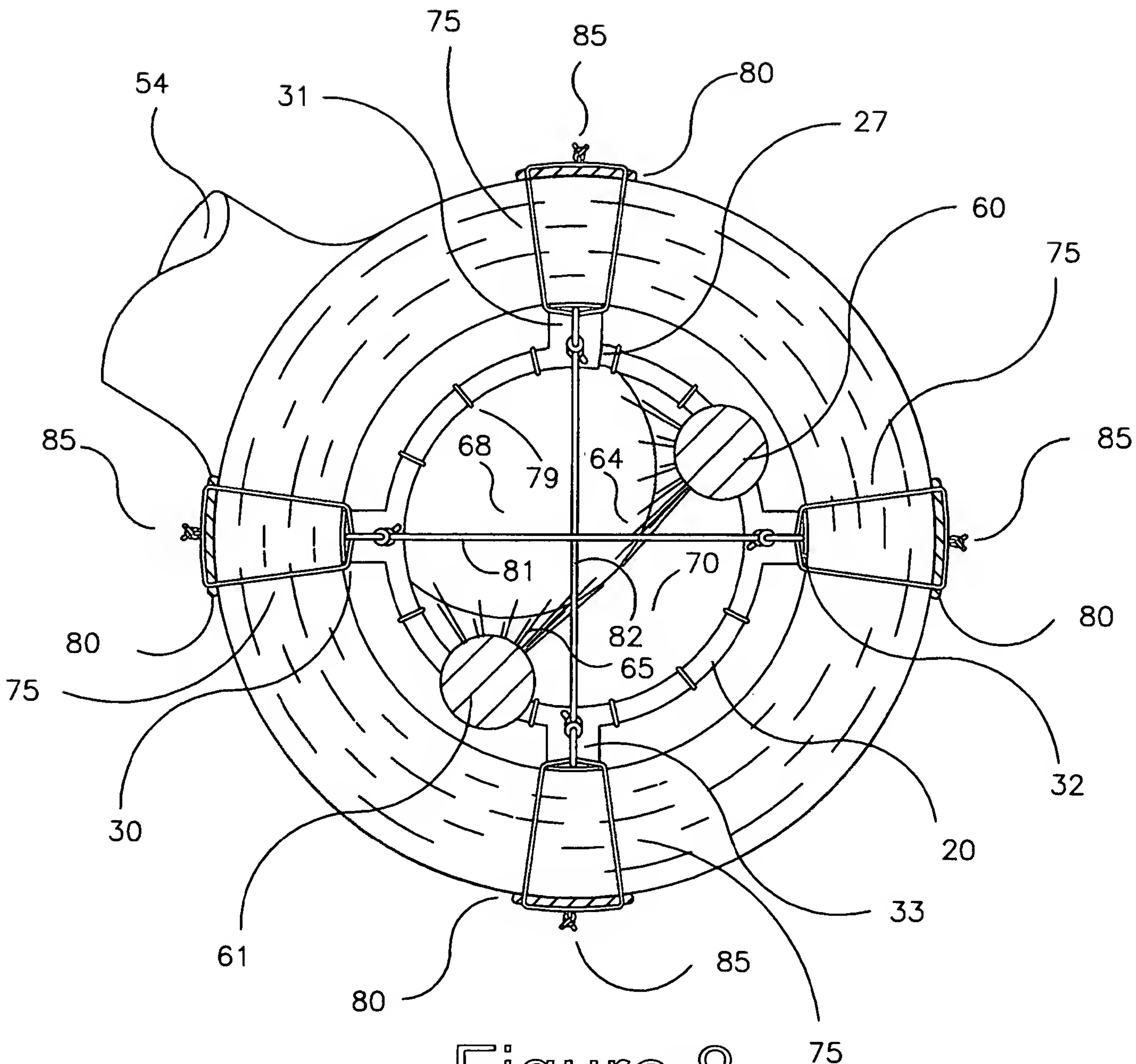
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Figure 8

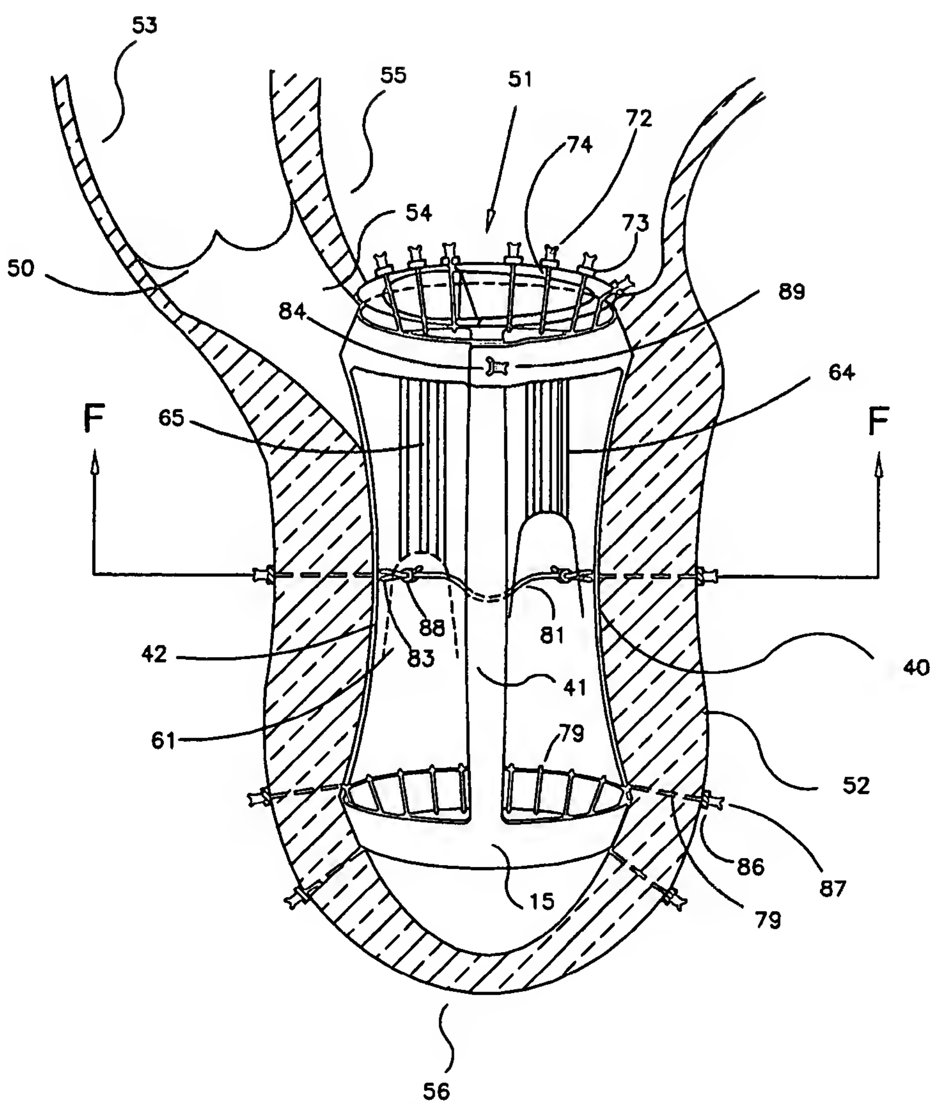

Figure 9

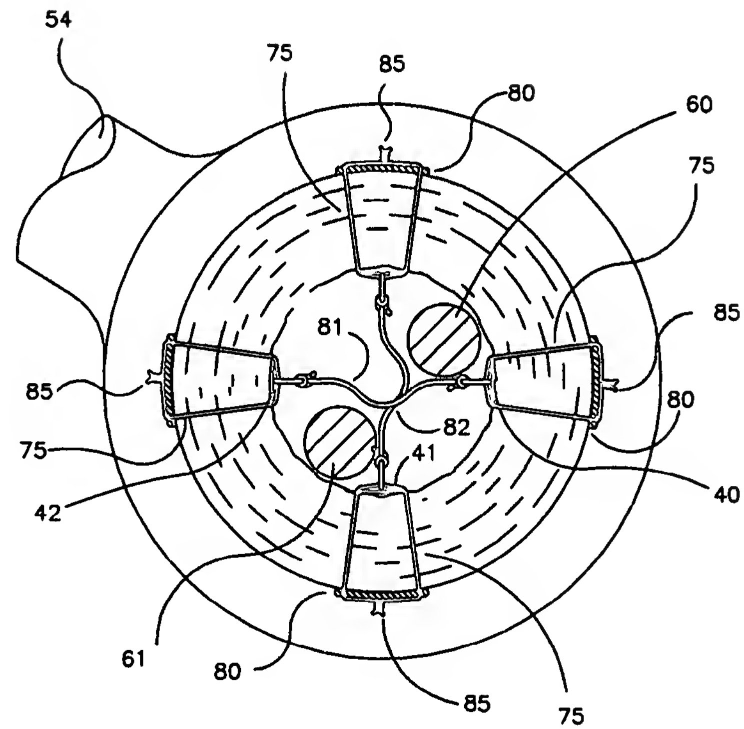

Figure 10

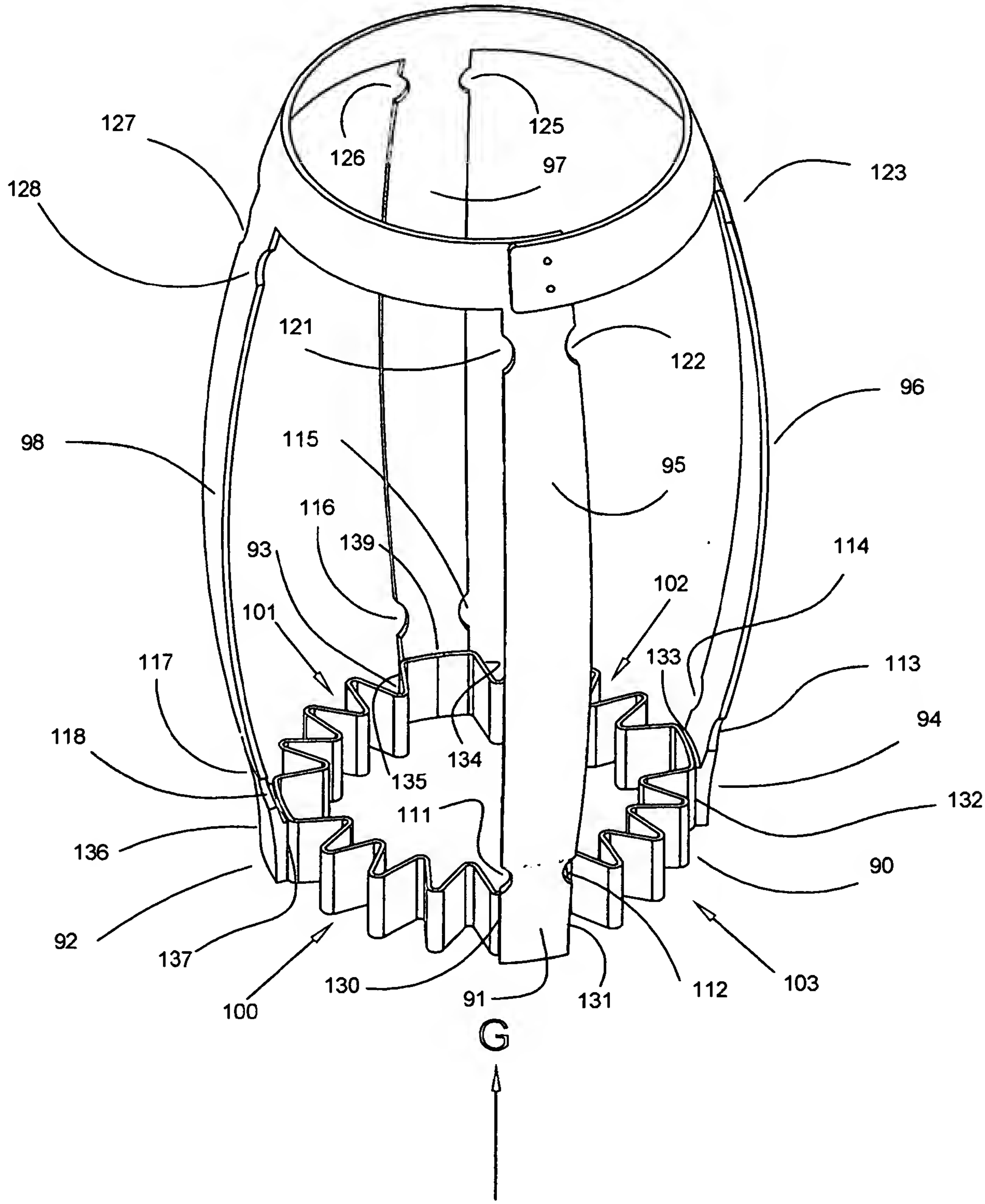

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Figure 11

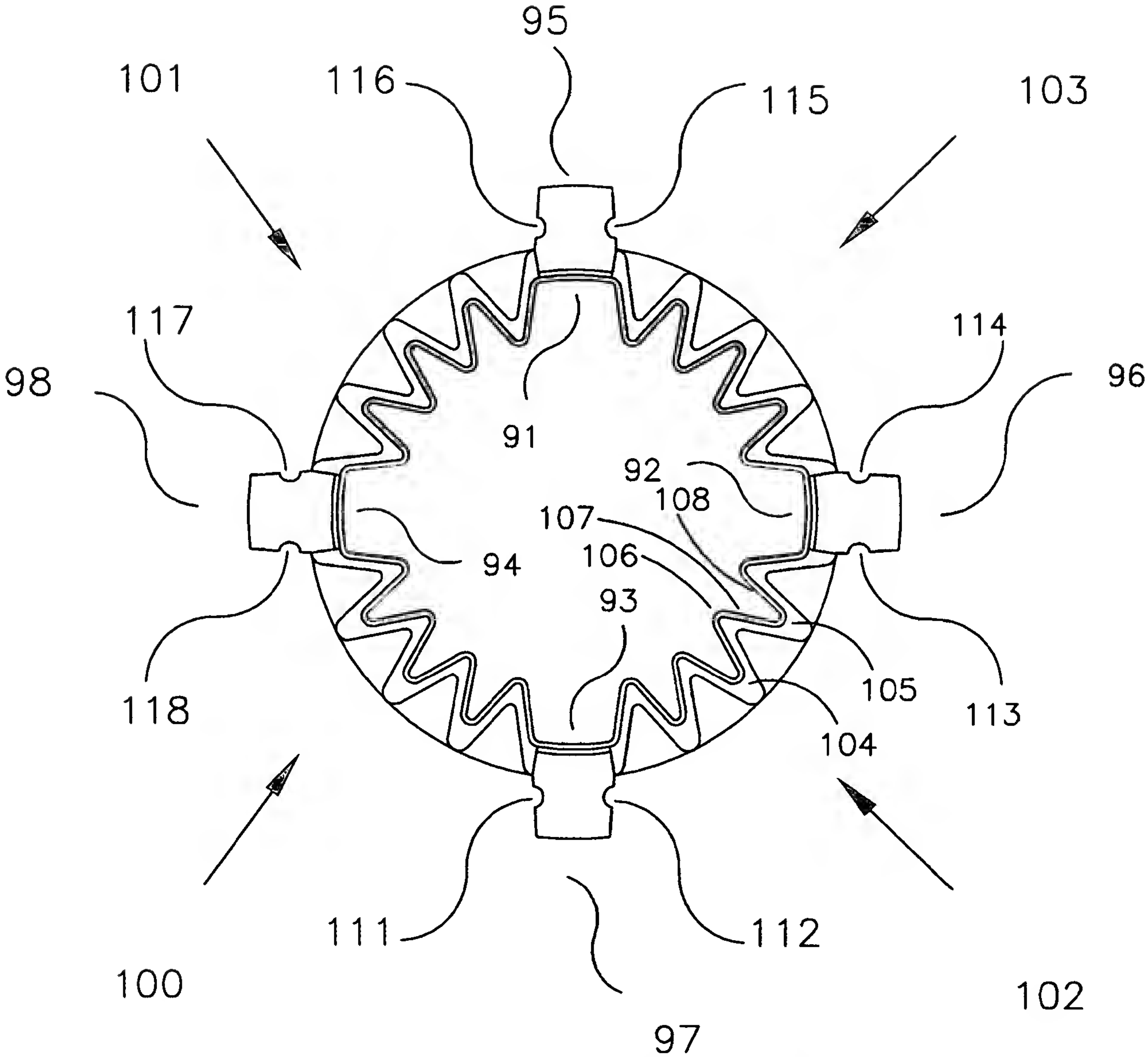

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Figure 12

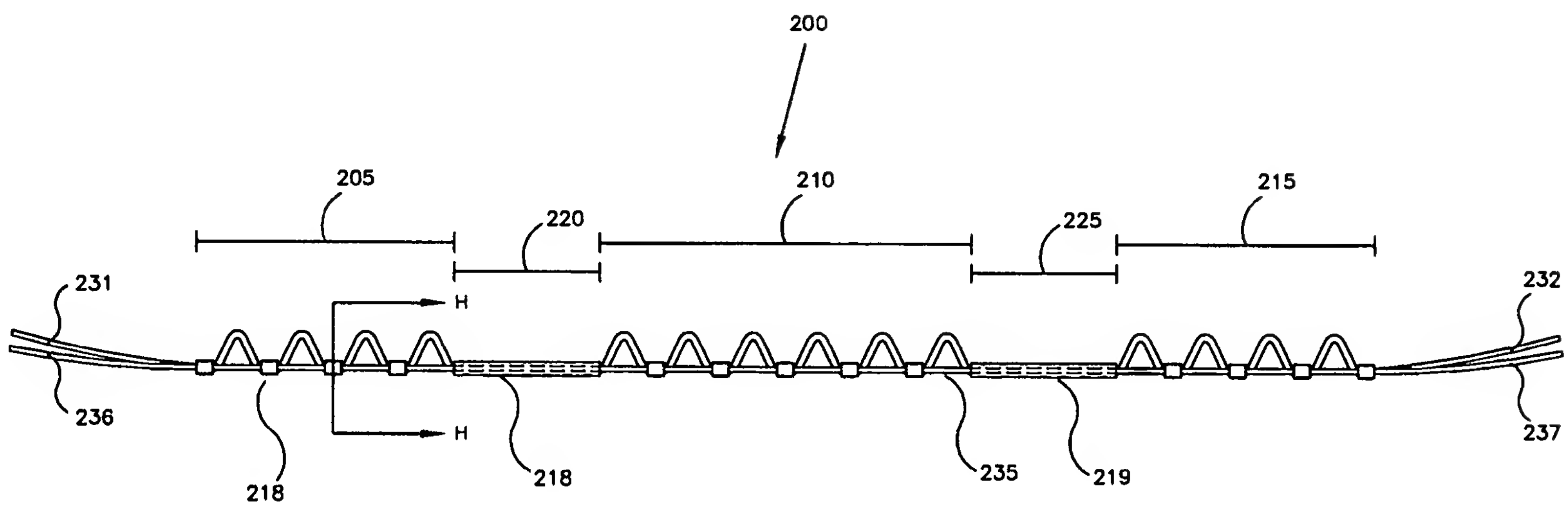
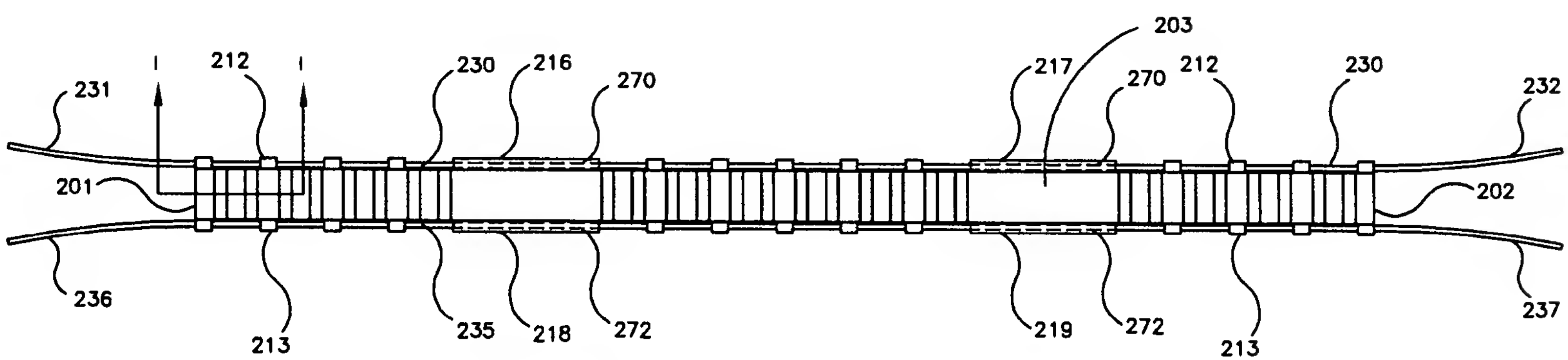


Figure 13



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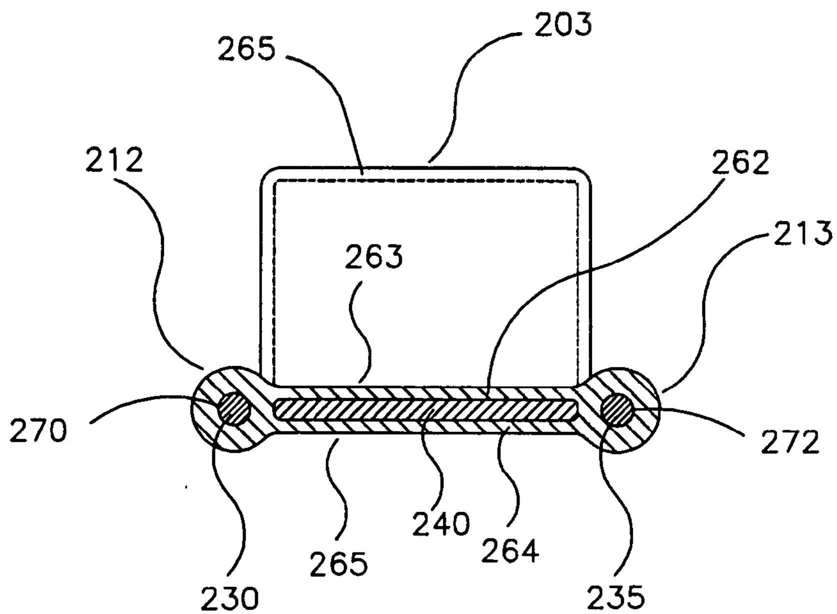


Figure 15

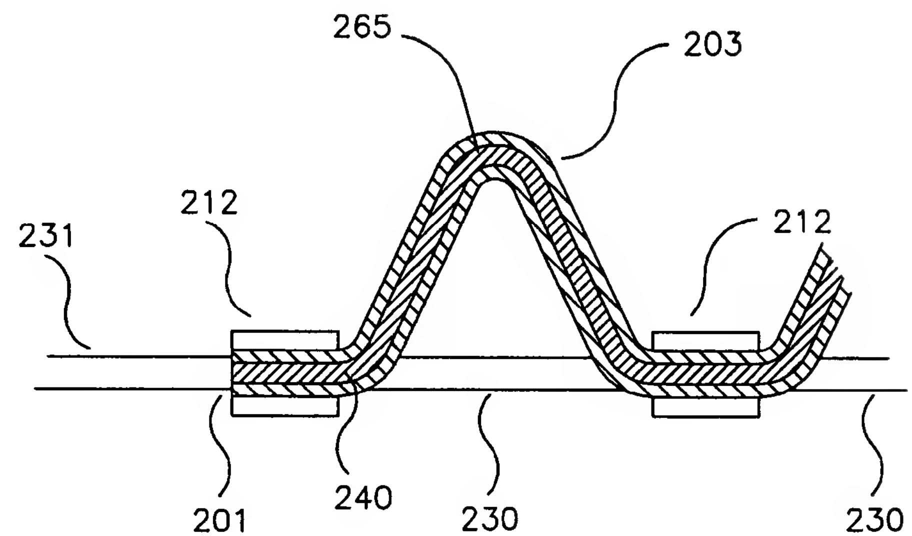
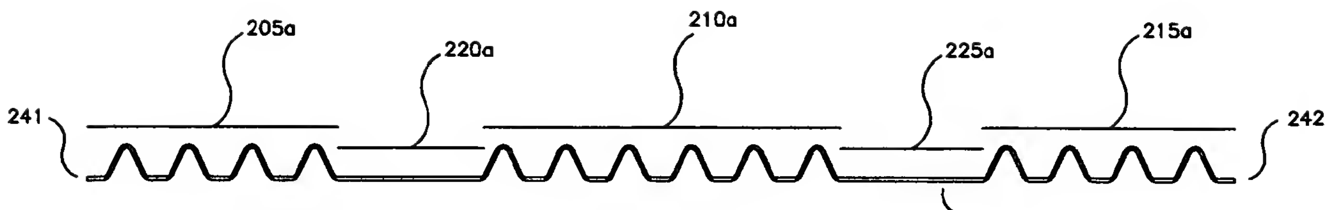


Figure 16



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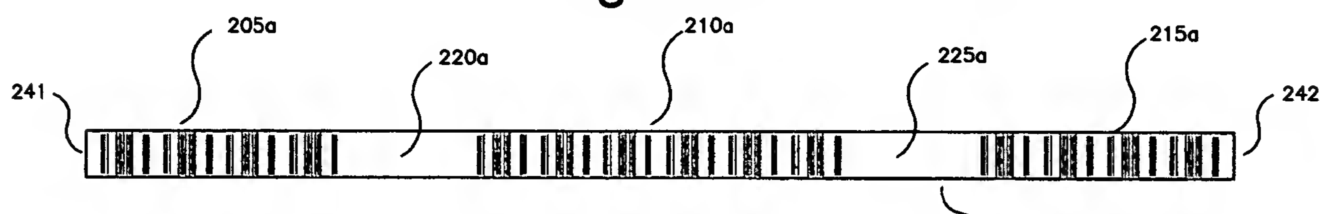

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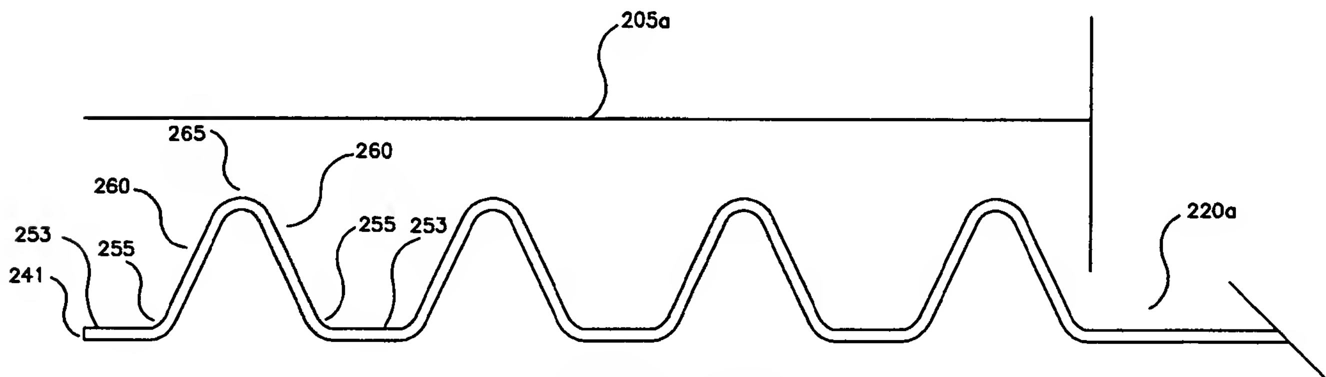

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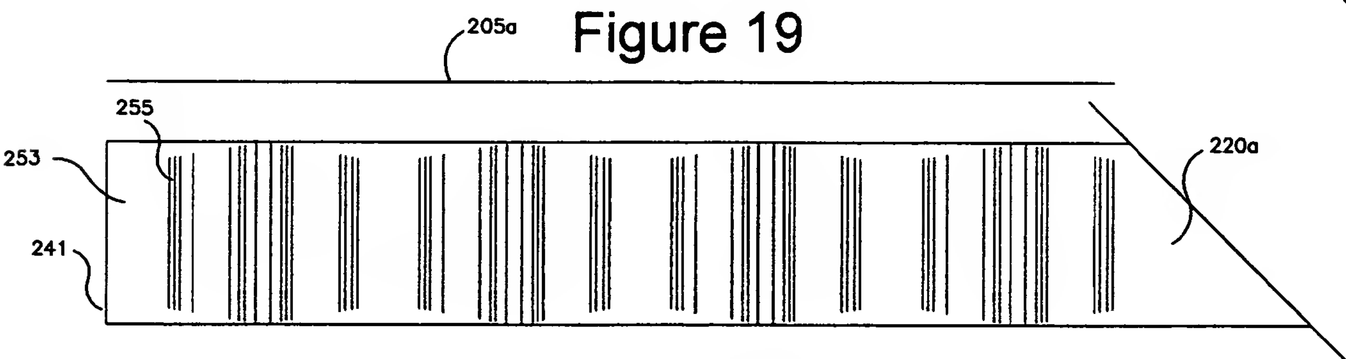

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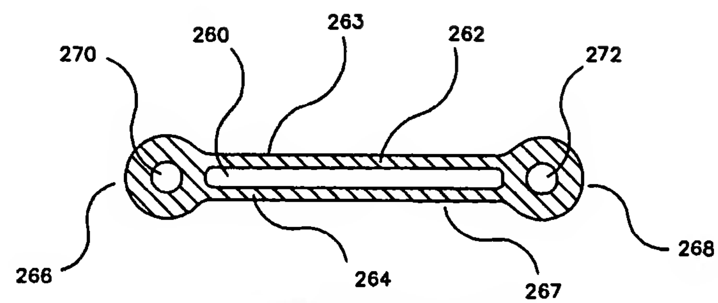

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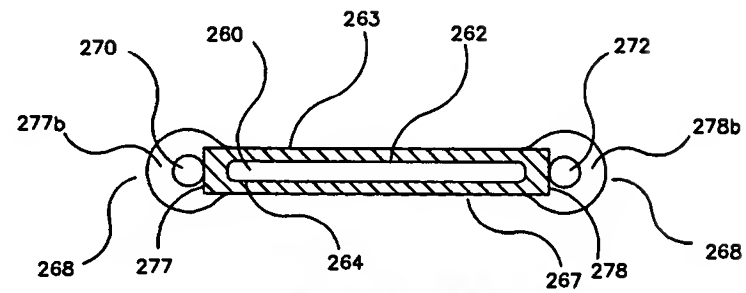

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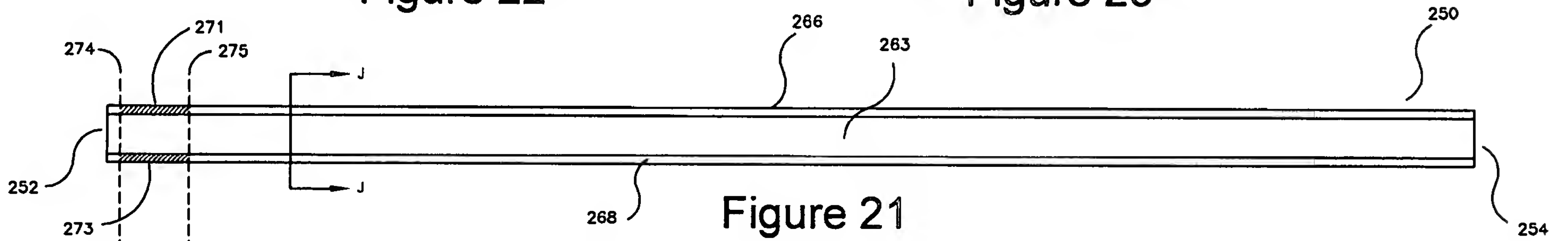

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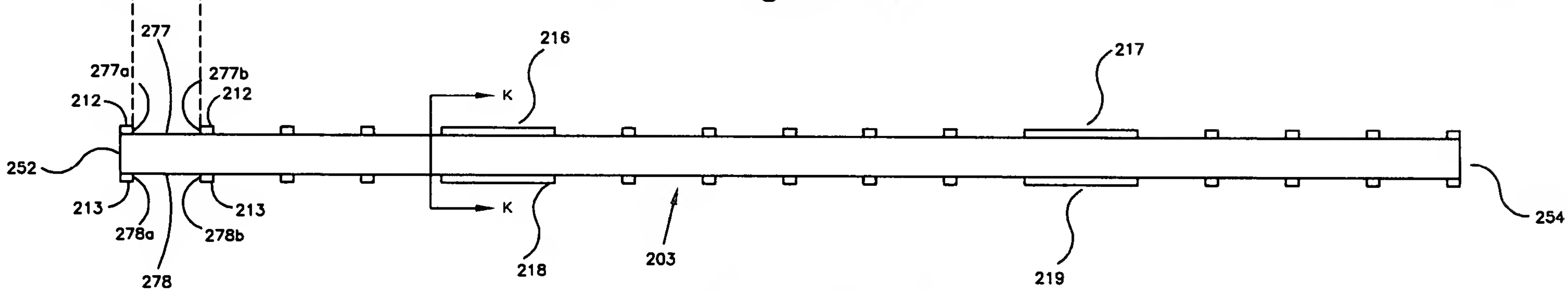

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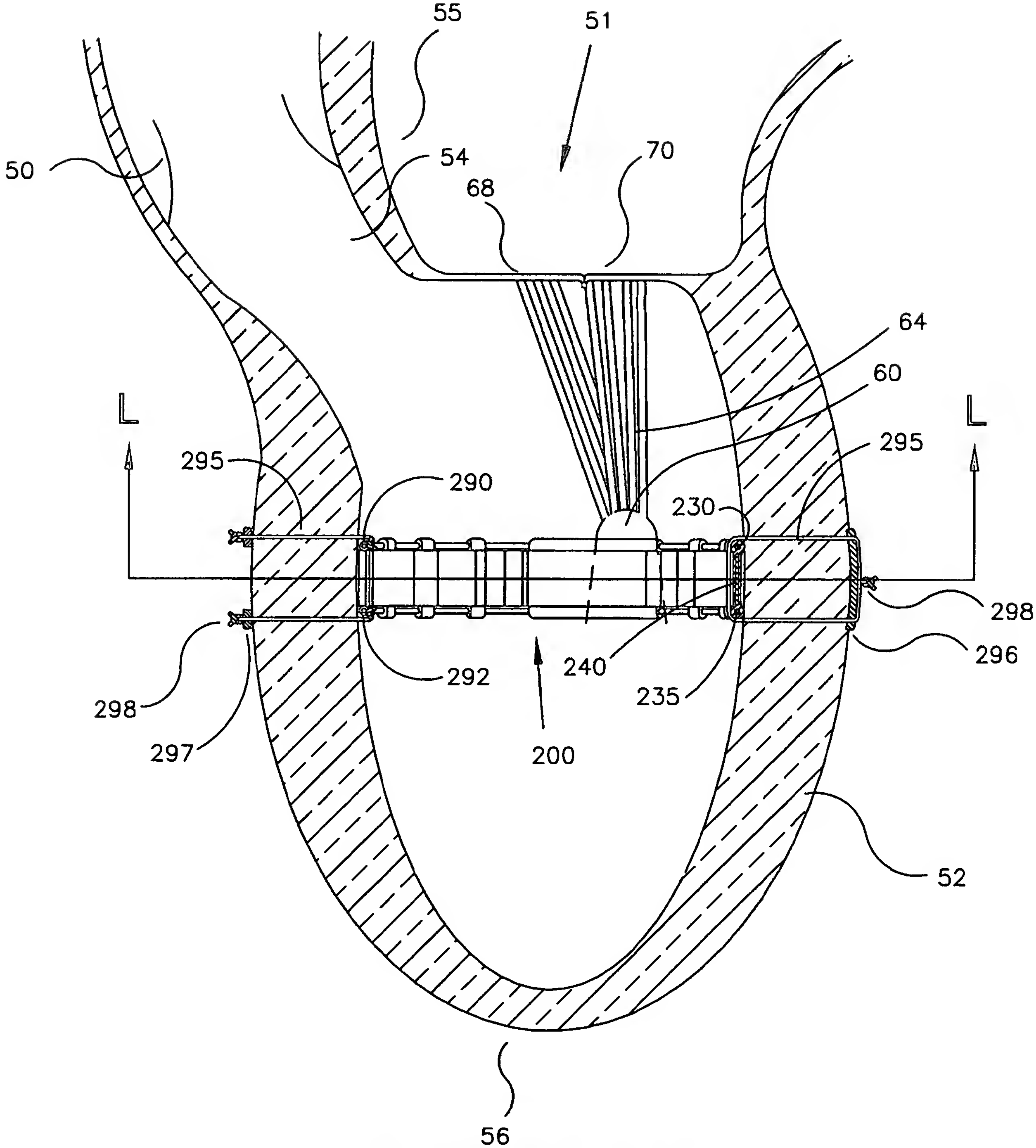
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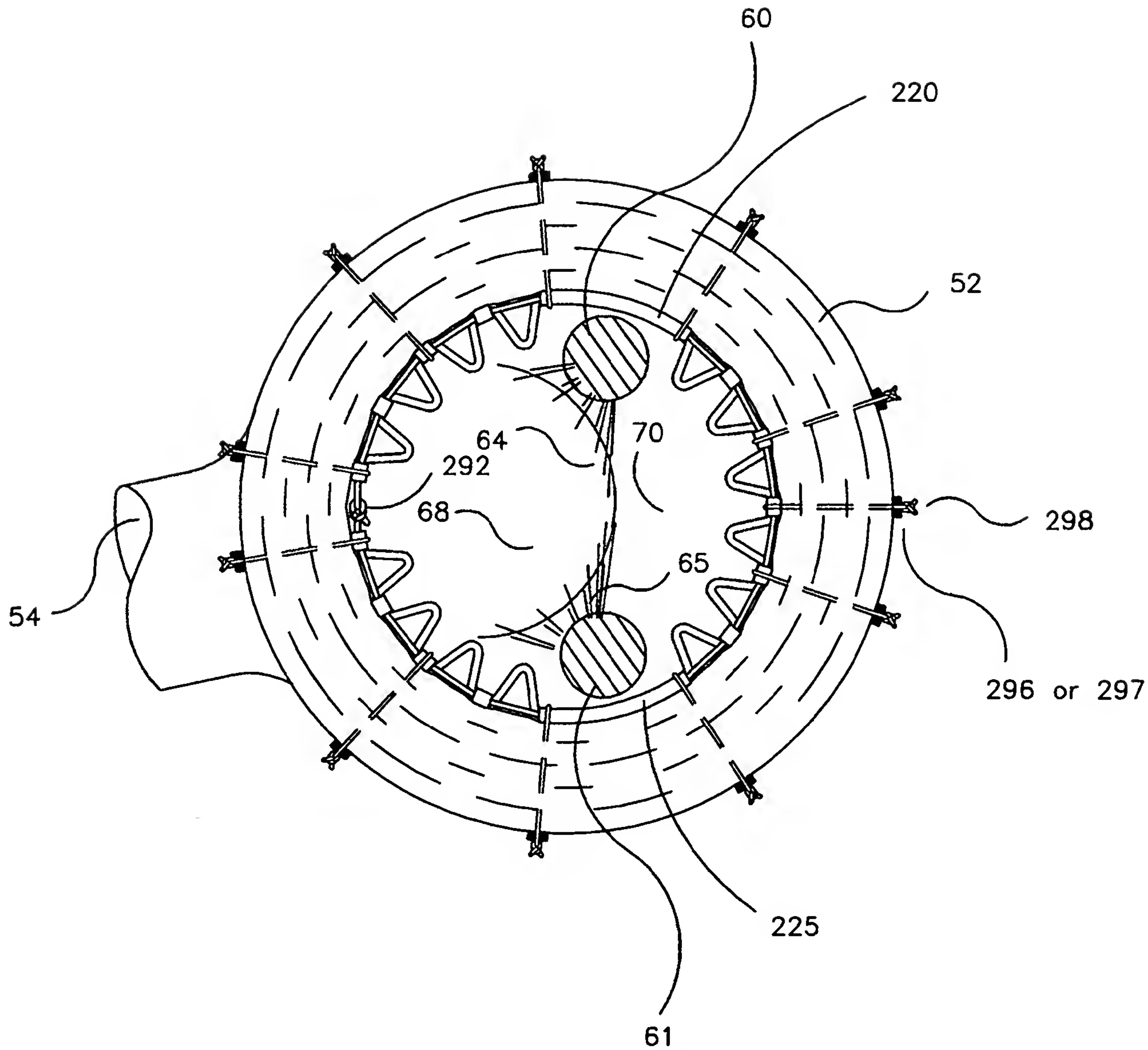
Figure 25



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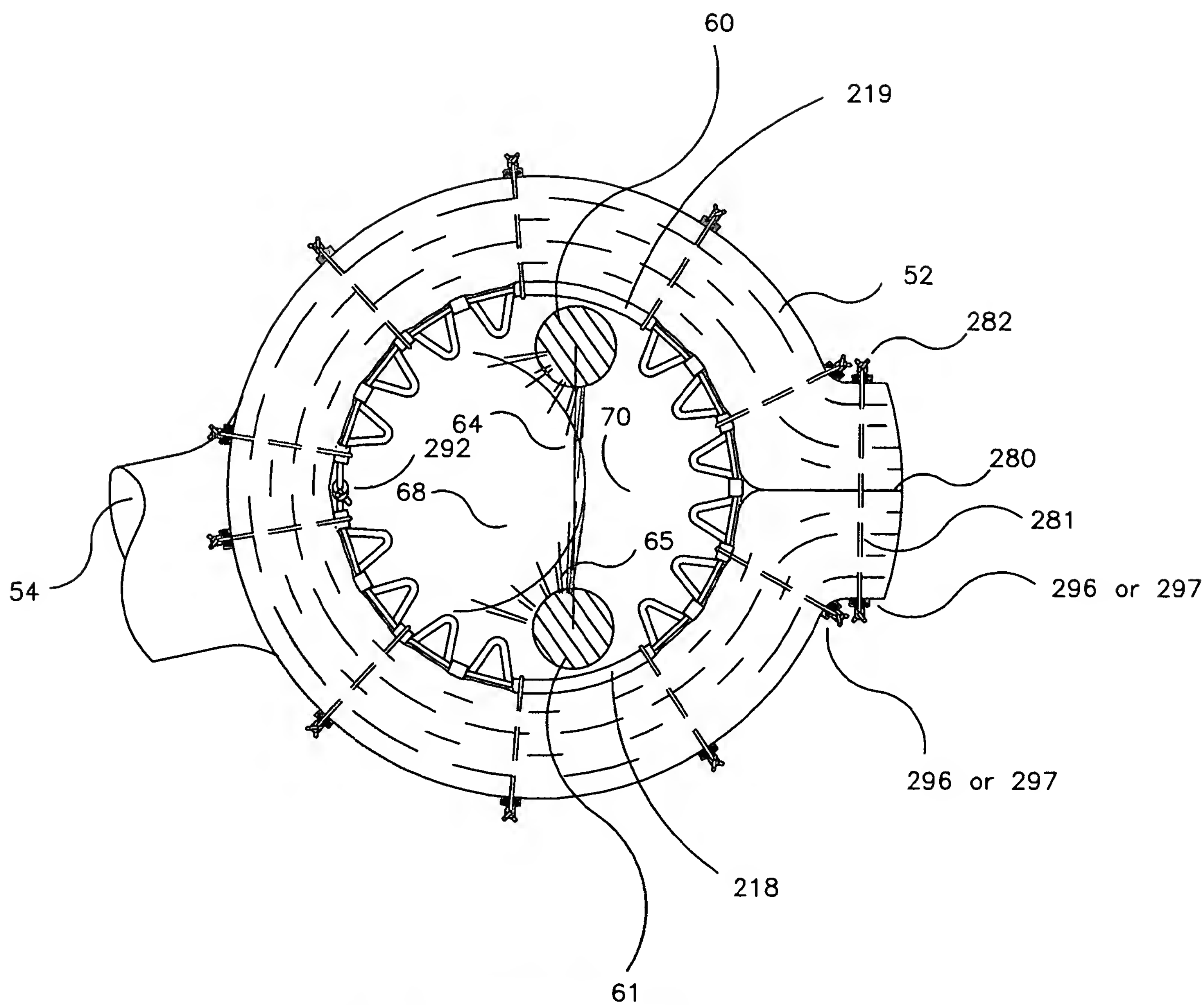
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Figure 27

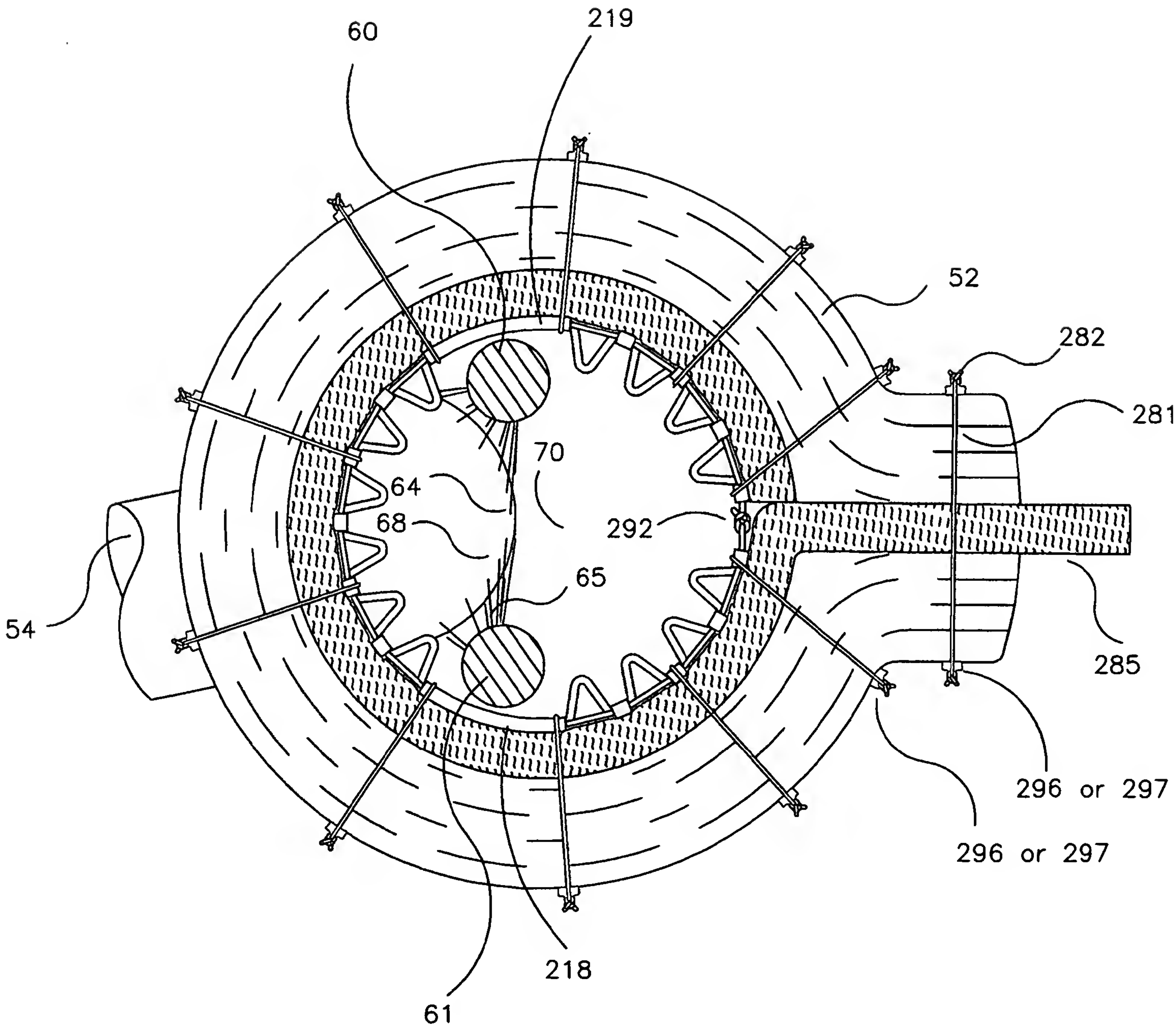
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Figure 28

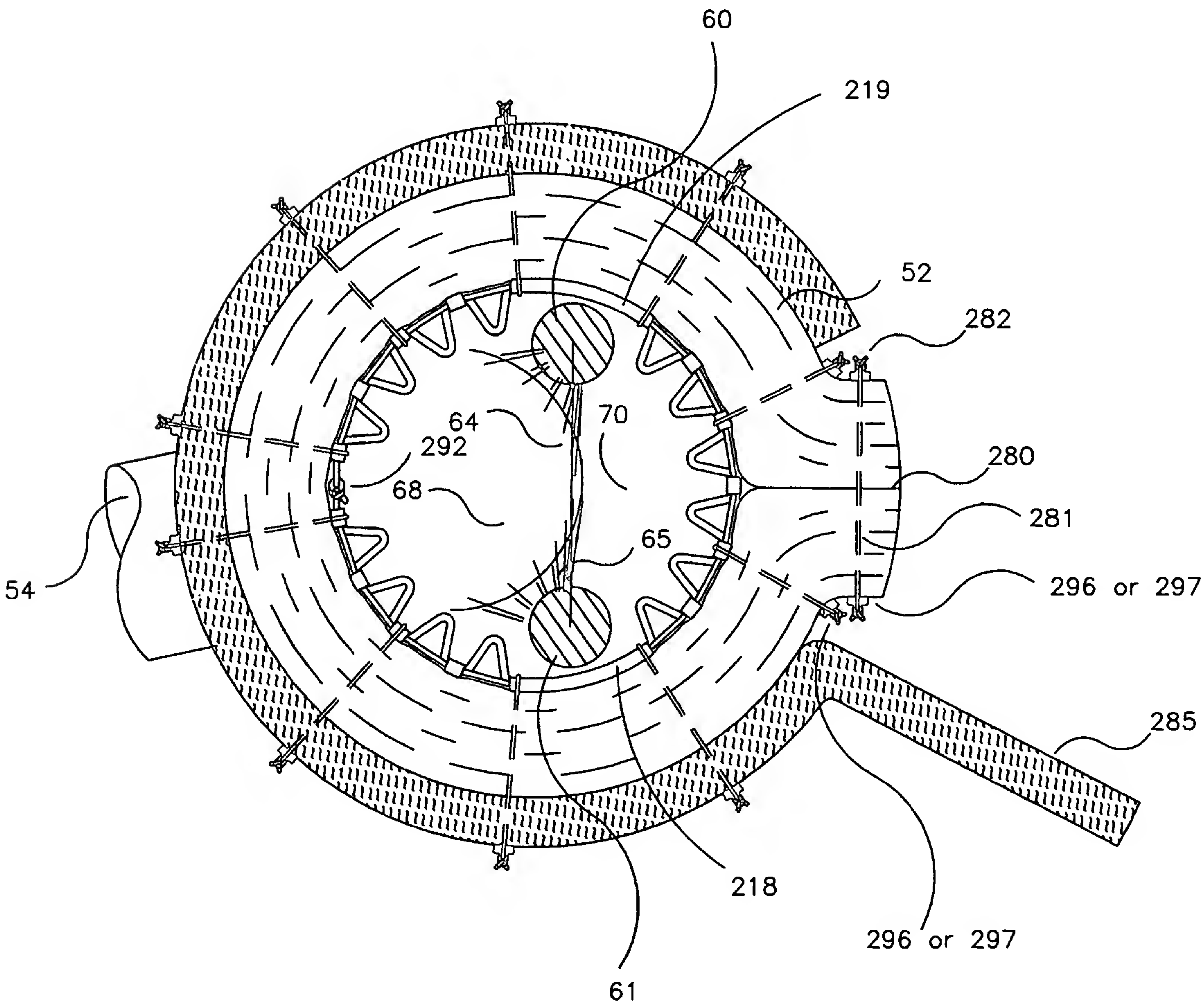

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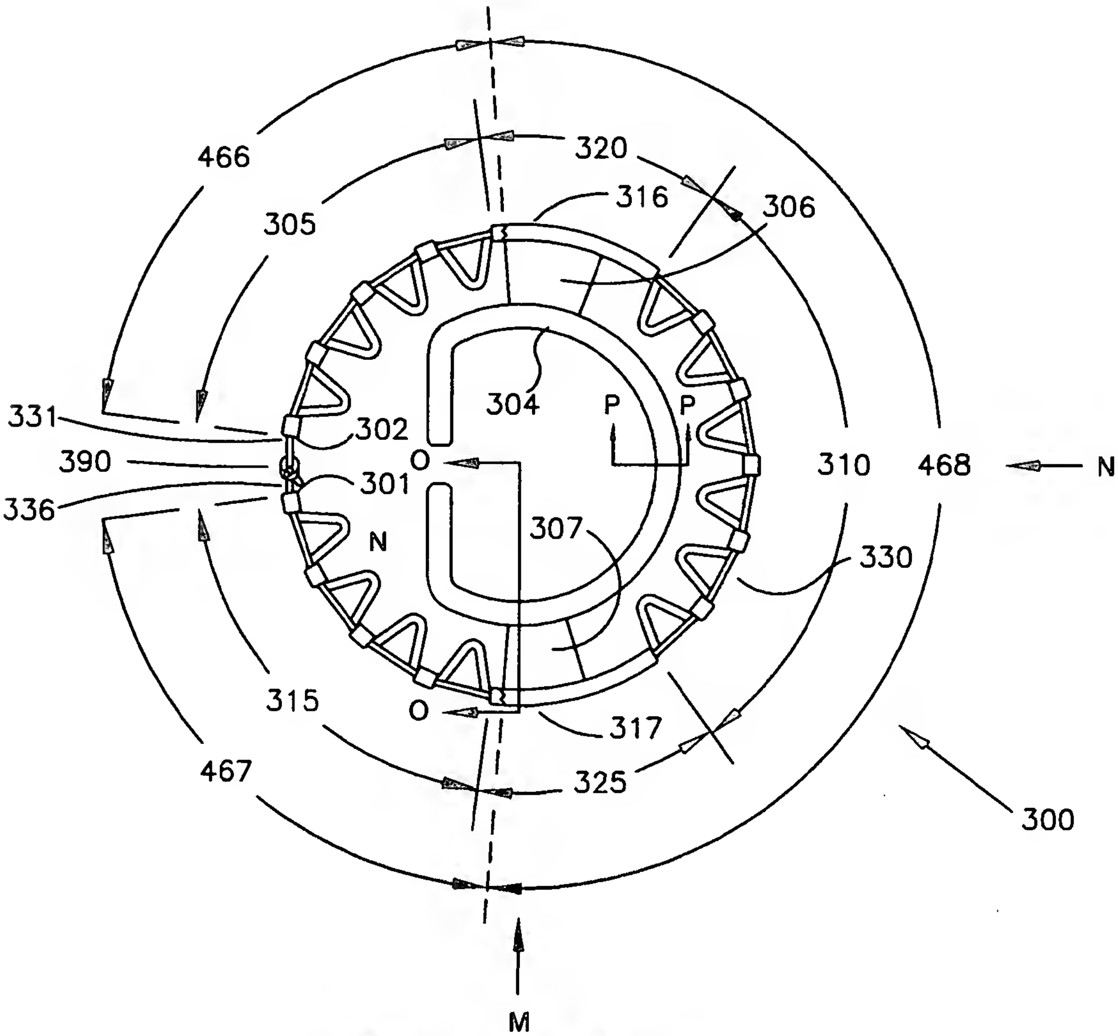
Figure 29



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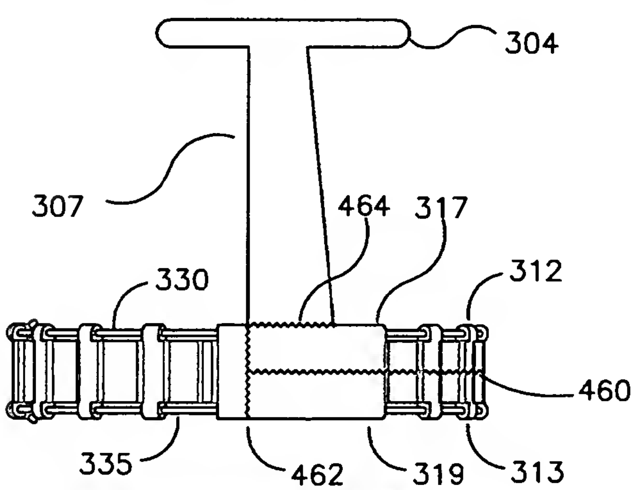

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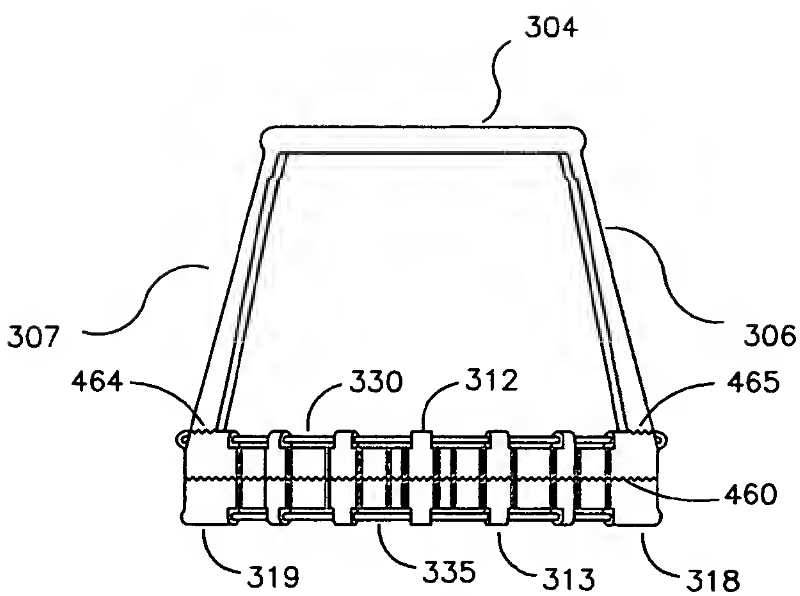

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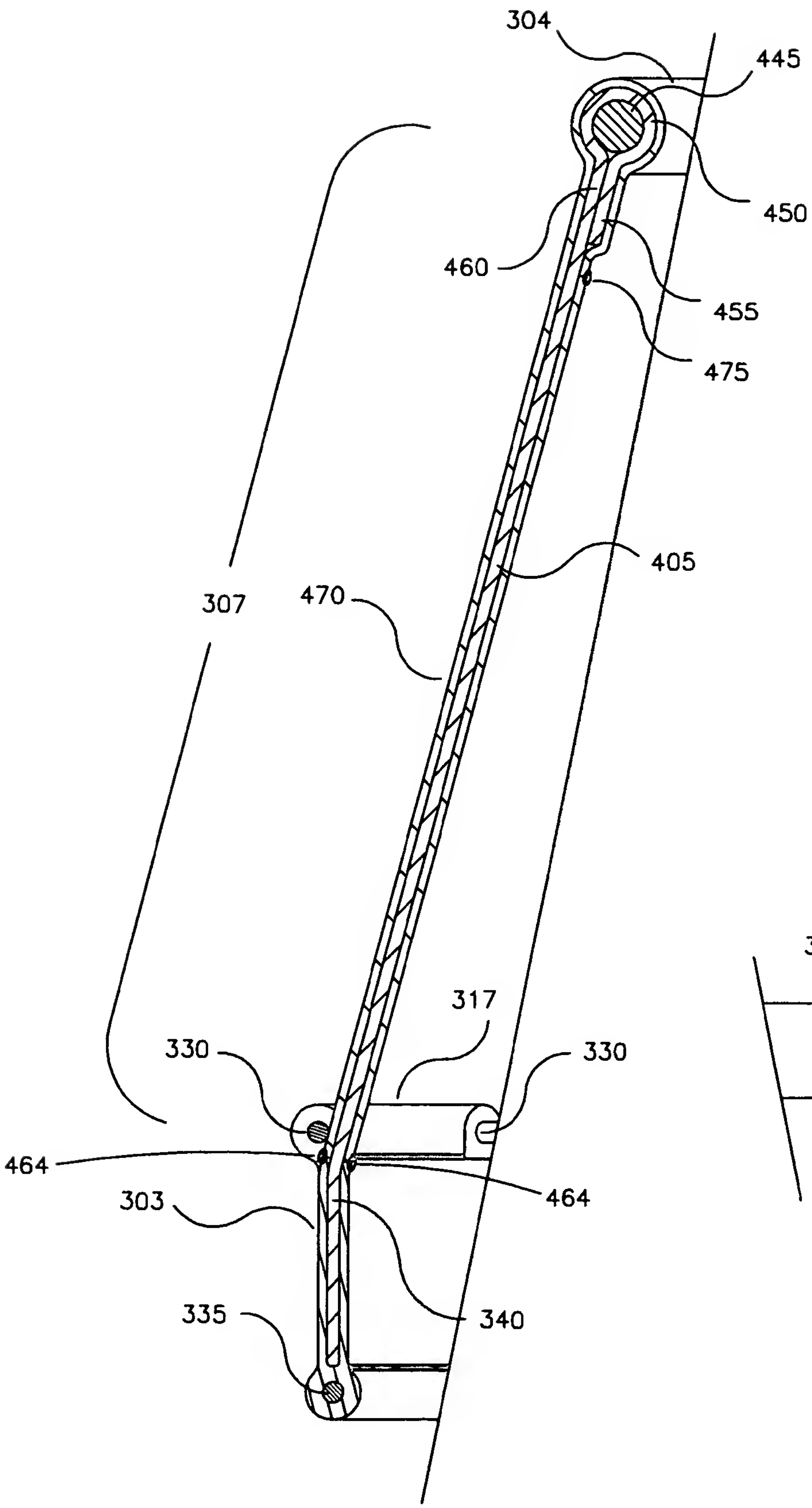

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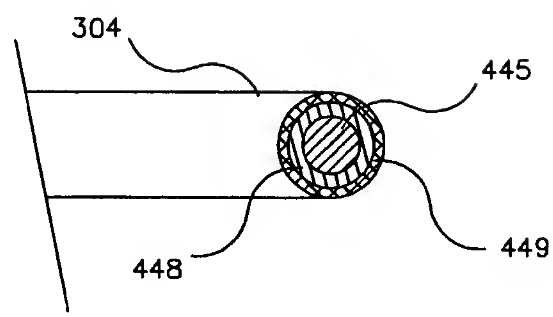

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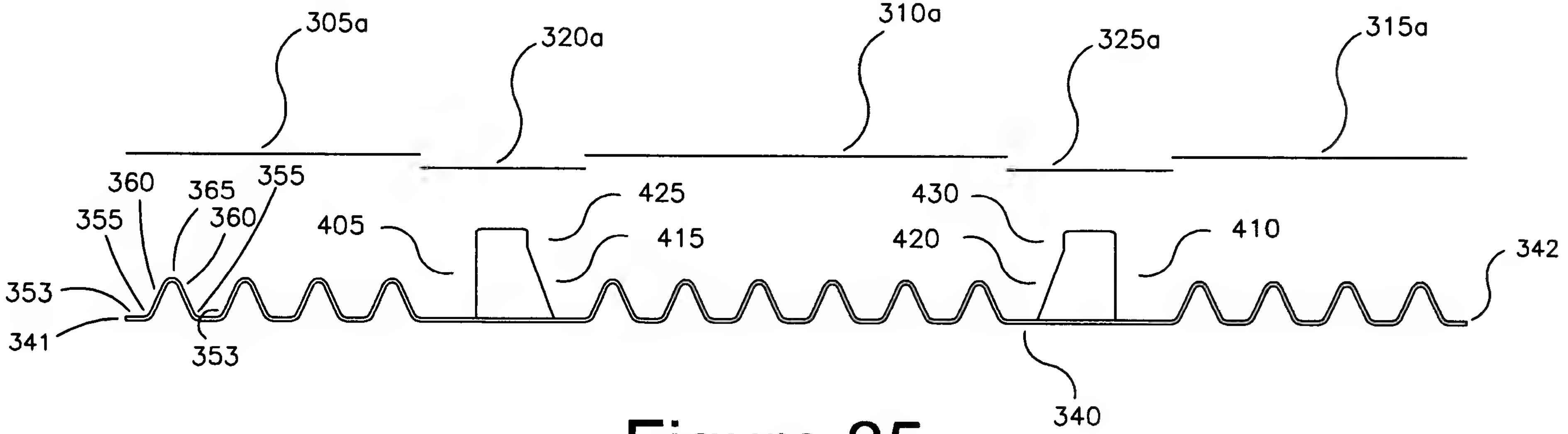
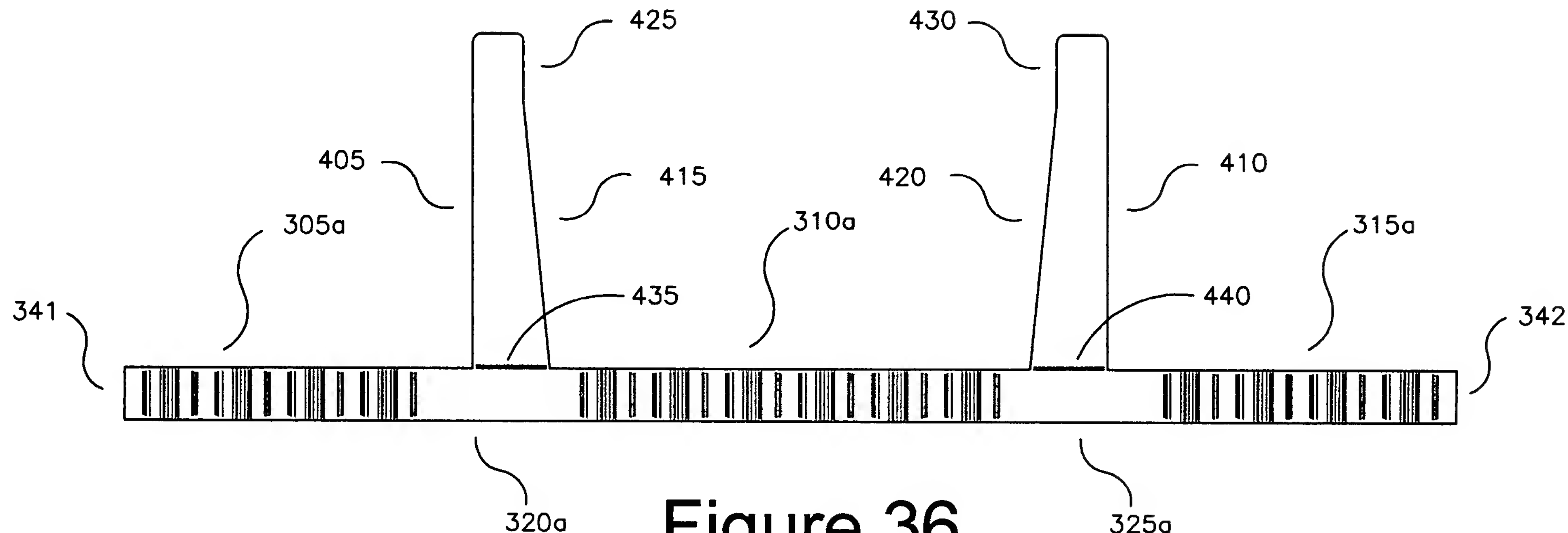


Figure 35



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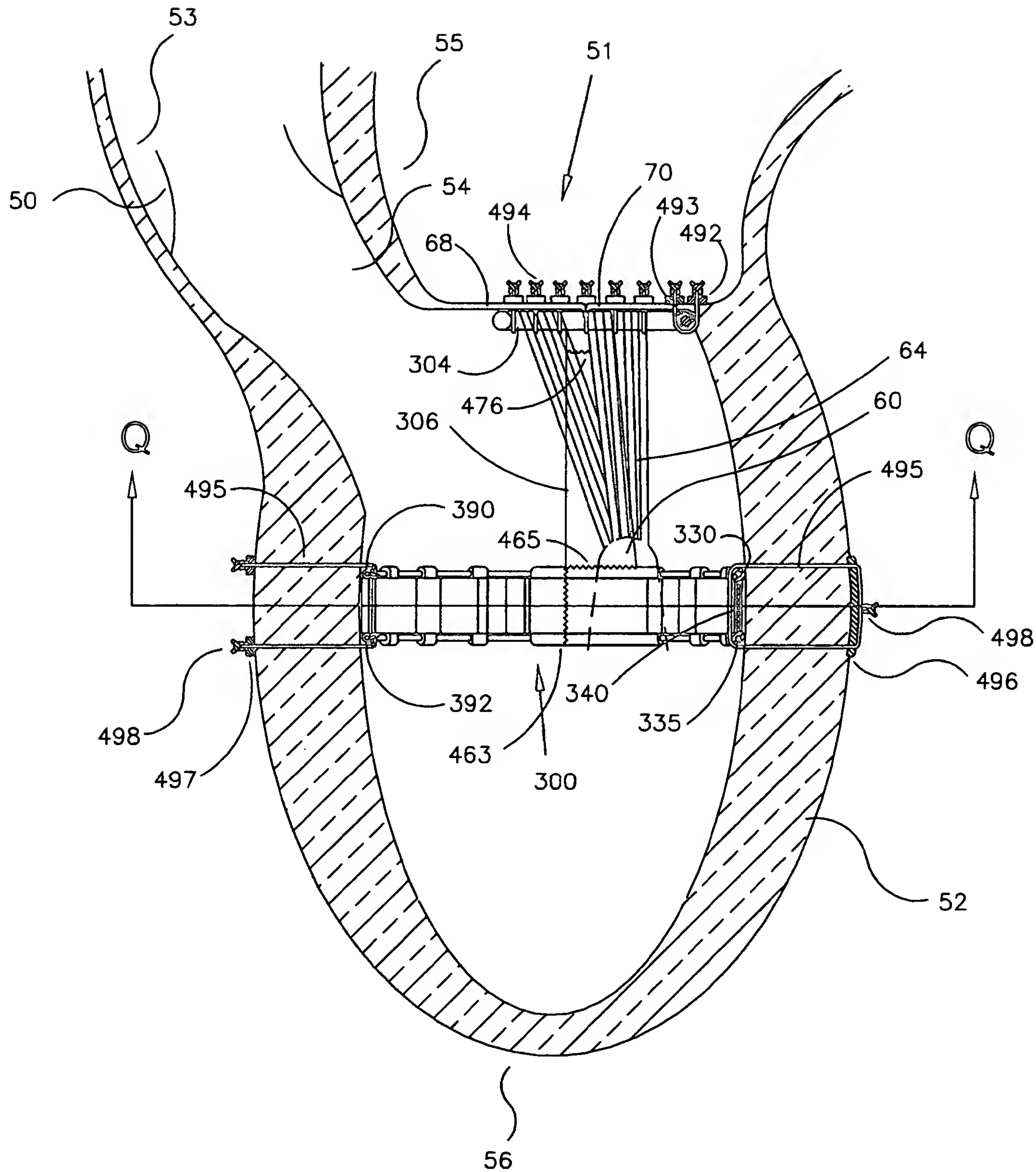

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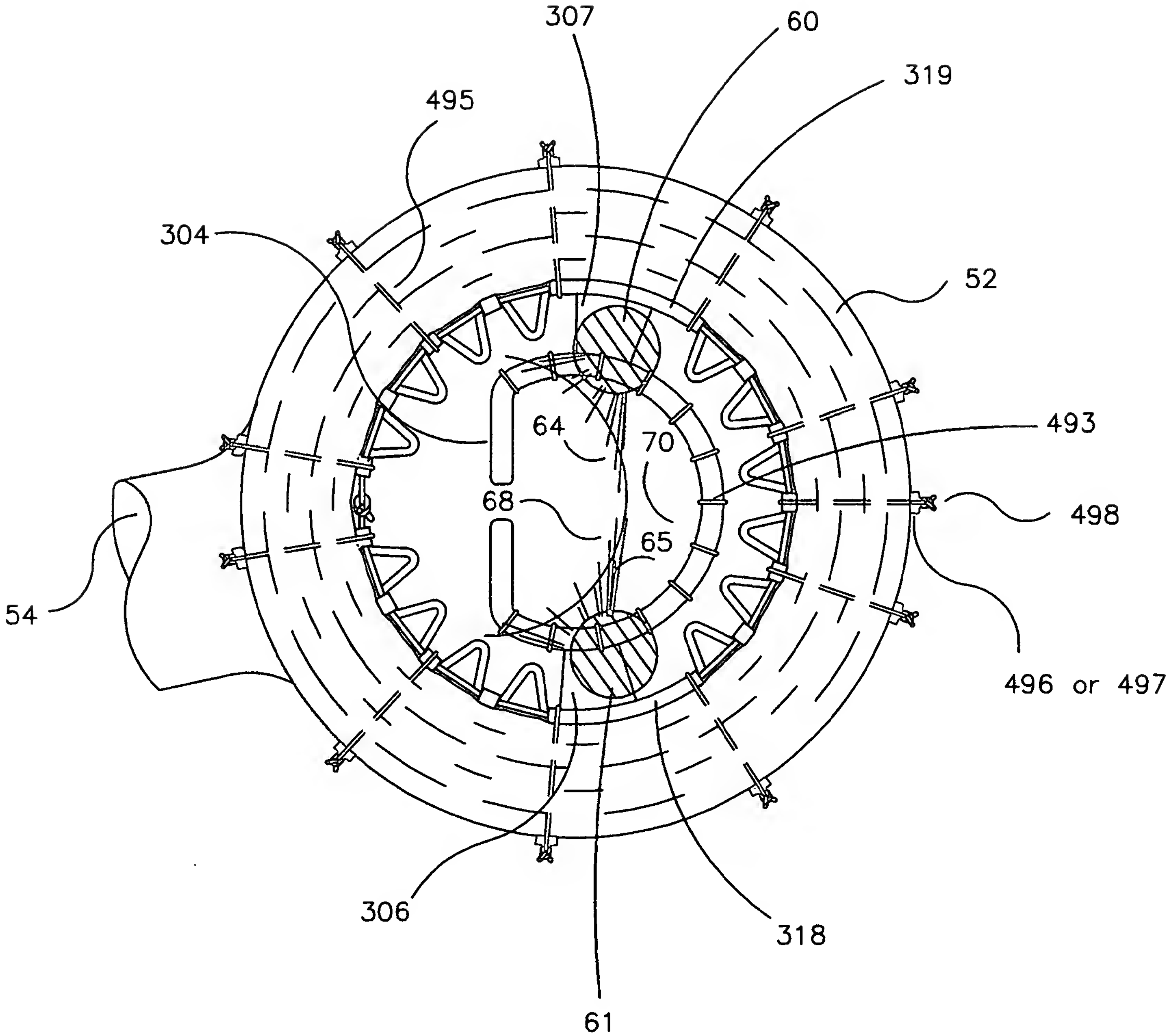
Figure 37



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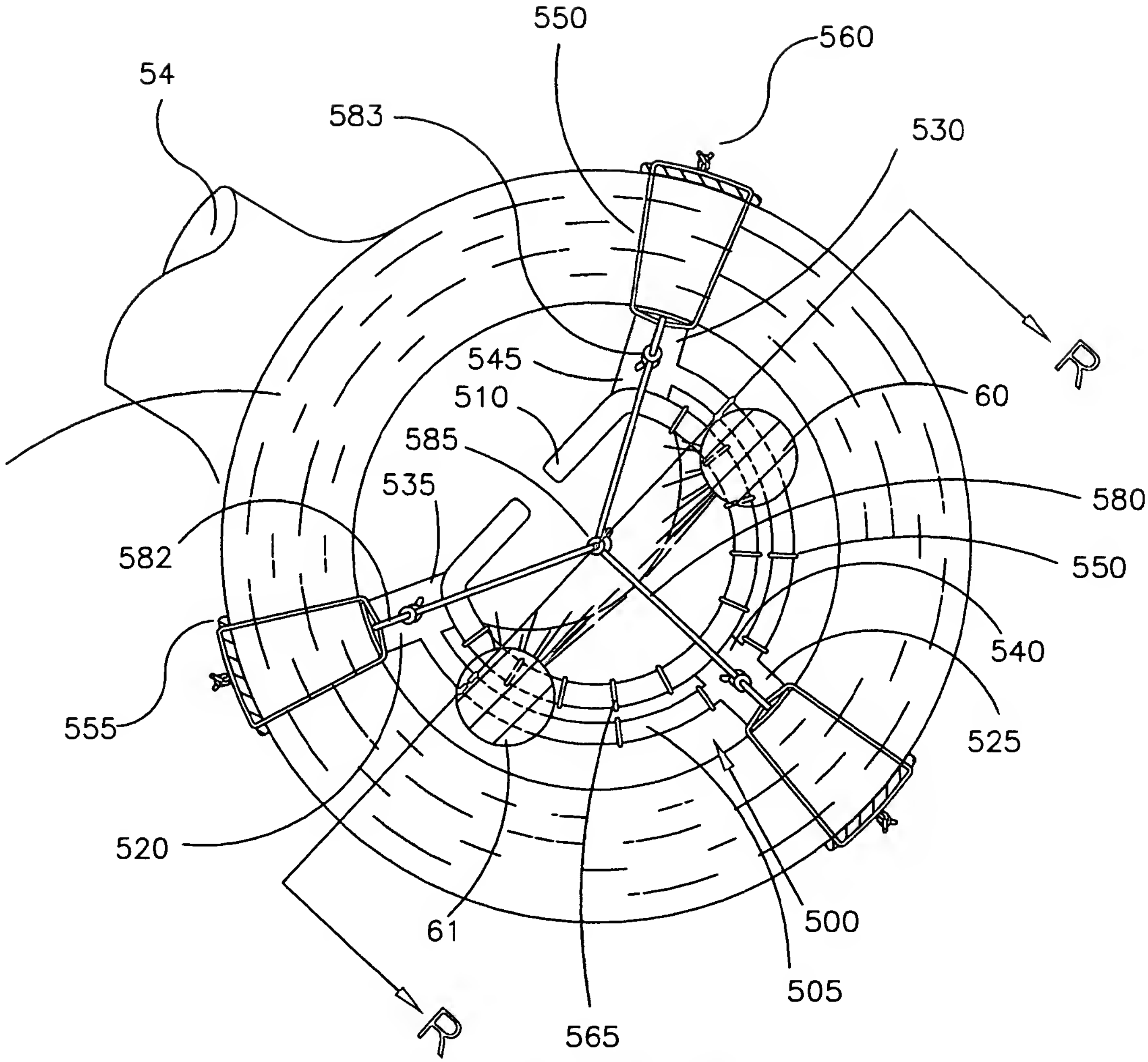
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Figure 39

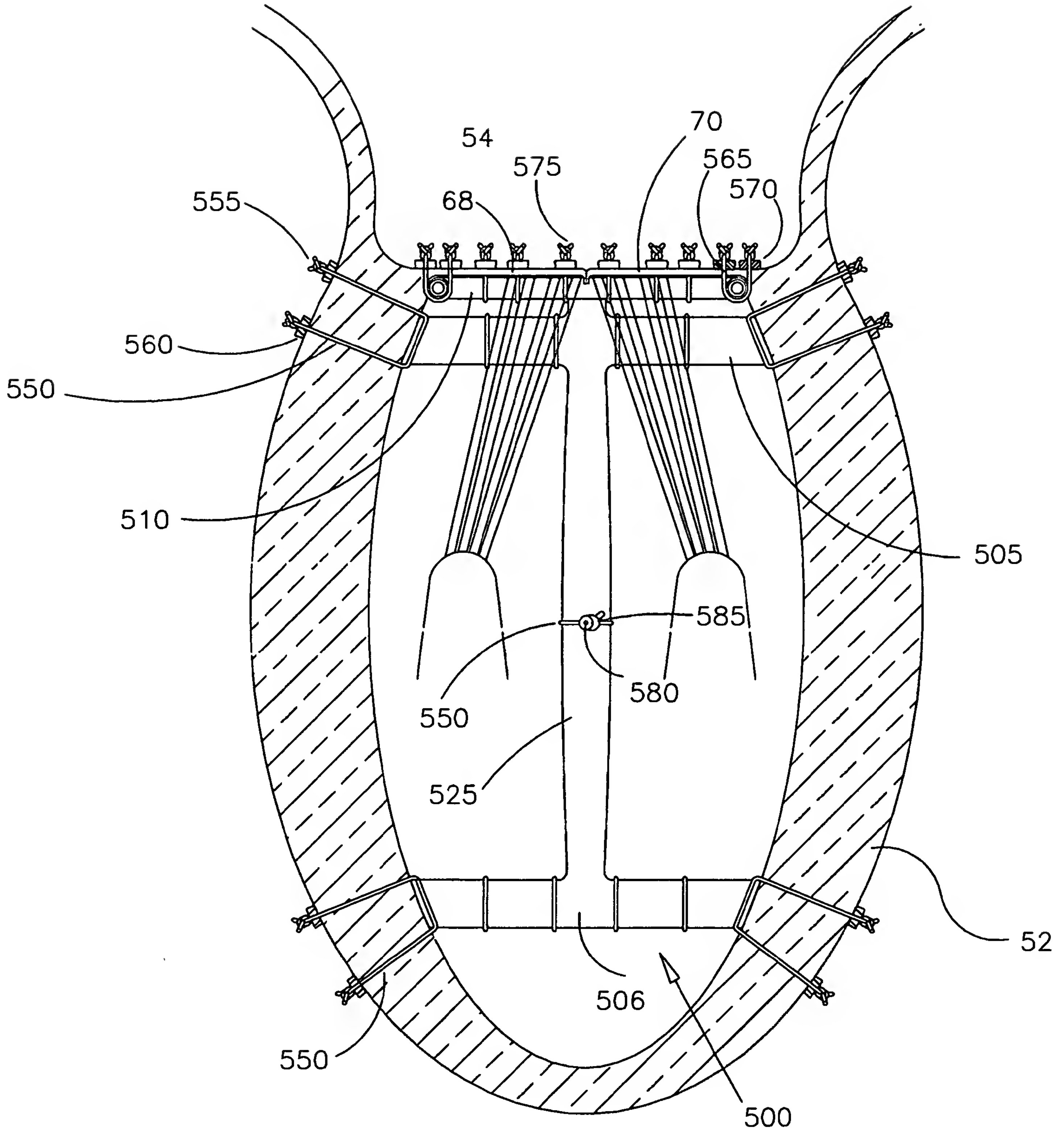

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Figure 40